



EG-Konformitätserklärung/EC Declaration of Conformity

gemäß Anhang III der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998
as per Annex III of Directive 98/79/EC of the European Parliament and Council of 27 October 1998
und/and

gemäß Anhang VI der Richtlinie 2011/65/EU des Europäischen Parlaments und des Rates vom 8. Juni 2011
as per Annex VI of Directive 2011/65/EU of the European Parliament and Council of 8 June 2011

Hersteller/Manufacturer: Roche Diagnostics GmbH

Adresse/Address: Sandhofer Strasse 116
68305 Mannheim
Germany

Die Roche Diagnostics GmbH erklärt, dass das Produkt/die Produktfamilie
Roche Diagnostics GmbH declares that the product/the product line

Produktname/Product name: **MagNA Pure 96 System**

Art.-Nr./Cat. No.: **refer to page 3 and the following**

Description:

Das MagNA Pure 96 Instrument dient zur automatisierten Aufreinigung von Nukleinsäuren im Bereich der In-vitro-Diagnostik. Das MagNA Pure 96 Instrument ist zur Verwendung in Verbindung mit bestimmten MagNA Pure 96 Kits vorgesehen. Weiterhin ist das MagNA Pure 96 System zur Verwendung durch professionelle Nutzer mit der automatisierten Arbeitsstation, dem Computer (Steuereinheit) mit der Betriebssoftware, dem Softwareprotokoll, dem Probenaufarbeitungs-Kit und den Verbrauchsmaterialien vorgesehen.

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.

auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 98/79/EG des Europäischen Parlaments und des Rates vom 27. Oktober 1998 über In-vitro-Diagnostica (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

to which this declaration relates fulfils the requirements of Directive 98/79/EC of the European Parliament and Council of 27 October 1998 on in-vitro diagnostic medical devices (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market).

und/and

Ab Serien-Nr./
Starting with Serial No.: 4355



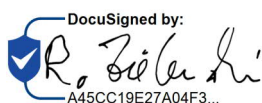
auf das/die sich diese Erklärung bezieht, den Forderungen der Richtlinie 2011/65/EU inklusive Artikel 4 des Europäischen Parlaments und des Rates vom 8. Juni 2011 betreffend Beschränkung der Verwendung bestimmter gefährlicher Stoffe gemäss Anhang II (Blei, Quecksilber, Cadmium, Sechswertiges Chrom, Polybromierte Biphenyle and Polybromierte Diphenylether) in Elektro- und Elektronikgeräten (bzw. seine Umsetzung in nationales Recht der Mitgliedsstaaten in welchen das Produkt vermarktet werden soll) entspricht.

to which this declaration relates fulfills the requirements of Directive 2011/65/EU including Article 4 of the European Parliament and Council of 8 June 2011 on the restriction of the use of certain hazardous substances according Annex II (lead, mercury, hexavalent chromium, cadmium, polybrominated biphenyls and polybrominated diphenyl ethers) in electrical and electronic equipment (and its relevant transposition into the national laws of the Member States in which the device is intended to be placed on the market).

Mannheim, 22 June 2020

Roche Diagnostics GmbH

ppa./on behalf of the company

DocuSigned by:

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Ralf Zielenski
Head of Quality
Centralised and Point of Care Solutions

ppa./on behalf of the company

DocuSigned by:

FC5EDEC1054B44C...

Dr. Stefan Scheib
Director Global Regulatory Affairs
Centralised and Point of Care Solutions

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Germany



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|---------------------------------|--------------|---|
| <u>Instrument:</u> | 06541089001: | MagNA Pure 96 Instrument |
| | 07381875001: | MagNA Pure 96 SW v3.0 |
| | 08423083001: | MagNA Pure 96 SW v3.1.0 |
| | 08816069001: | MagNA Pure 96 SW v3.1.1 |
| | 09262415001: | MagNA Pure 96 SW v3.2.0 |
| | 06638996001: | MagNA Pure 96 LightCycler® 480 Adapter |
| | 06639003001: | MagNA Pure 96 Archive Plate Adapter 4S |
| | 06541119001: | MagNA Pure 96 Drop Catcher |
| | 06541127001: | MagNA Pure 96 Reagent Loop Unit |
| | 06541143001: | MagNA Pure 96 Barcode Scanner |
| | 06541151001: | MagNA Pure 96 Tip Rack |
| | 06541178001: | MagNA Pure 96 Bottle Rack |
| | 06541194001: | MagNA Pure 96 Needle Set of 4 |
| | 06541208001: | MagNA Pure 96 Purification Rack |
| | 06541224001: | MagNA Pure 96 Reagent Rack |
| | 06541259001: | MagNA Pure 96 Waste Rack |
| | 06541267001: | MagNA Pure 96 Internal Waste Container |
| | 06541275001: | MagNA Pure 96 Waste Cover |
| | 06541283001: | MagNA Pure 96 Plate Holder |
| <u>System Fluid:</u> | 06430112001: | MagNA Pure 96 System Fluid (Internal Container) |
| | 06640729001: | MagNA Pure 96 System Fluid (External) |
| <u>Consumables/Disposables:</u> | 06241620001: | MagNA Pure Tip 1000µL |
| | 06241603001: | MagNA Pure 96 Processing Cartridge |
| | 06241611001: | MagNA Pure 96 Output Plate |
| <u>Kits:</u> | 06543588001: | MagNA Pure 96 DNA and Viral NA Small Volume Kit |
| | 06374891001: | MagNA Pure 96 DNA and Viral NA Large Volume Kit |
| <u>Reagents:</u> | 06374921001: | MagNA Pure 96 Bacteria Lysis Buffer |
| | 06374913001: | MagNA Pure 96 External Lysis Buffer |
| | 06640702001: | MagNA Pure 96 DNA Tissue Lysis Buffer |
| <u>IC Tube:</u> | 06374905001: | MagNA Pure 96 Internal Control Tubes |
| <u>Software protocol:</u> | 08779996001: | Pathogen Universal 200, SW v4.0 |
| | 08780013001: | Pathogen Universal 500, SW v4.0 |
| | 08780021001: | Pathogen Universal 1000, SW v4.0 |
| | 08780030001: | Viral NA Plasma SV, SW v4.0 |
| | 08780048001: | Viral NA Plasma LV, SW v4.0 |
| | 08780056001: | Viral NA Plasma LV 1000, SW v4.0 |
| | 08780064001: | Viral NA Plasma ext lys SV, SW v4.0 |
| | 08780099001: | Viral NA Plasma ext lys LV, SW v4.0 |
| | 08780102001: | Viral NA Universal SV, SW v4.0 |
| | 08780129001: | Viral NA Universal LV, SW v4.0 |
| | 08780137001: | Viral NA Universal LV 1000, SW v4.0 |
| | 08780145001: | DNA Blood ds SV, SW v2.0 |

Software protocol continued:

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| 08780153001: | DNA Blood SV, SW v4.0 |
| 08780161001: | DNA Blood LV, SW v4.0 |
| 08780170001: | DNA Blood LV 1000, SW v4.0 |
| 08780188001: | DNA Blood ext lys SV, SW v4.0 |
| 08780196001: | DNA Blood ext lys LV, SW v4.0 |
| 08780200001: | DNA Cells SV, SW v4.0 |
| 08780218001: | DNA Cells LV, SW v4.0 |
| 08780226001: | DNA Tissue SV, SW v5.0 |
| 08780234001: | DNA Tissue LV, SW v4.0 |
| 08780242001: | DNA FFPE SV, SW v4.0 |
| 08780269001: | cfNA ss 2000, SW v5.0 |
| 08780277001: | cfNA ss 4000, SW v5.0 |
| 08780285001: | cfNA ds 2000, SW v5.0 |
| 08780293001: | cfNA ds 4000, SW v5.0 |
| 08780315001: | Cellular RNA LV, SW v4.0 |
| 08780323001: | RNA Blood LV 400, SW v4.0 |
| 08780331001: | RNA Blood LV 800, SW v4.0 |
| 08780340001: | RNA PAXgene LV, SW v4.0 |
| 08780358001: | RNA PAXgene Half Tube LV, SW v4.0 |
| 08780366001: | RNA Tissue FF Standard LV, SW v4.0 |
| 08780374001: | RNA Tissue FF High LV, SW v4.0 |
| 08780382001: | RNA Tissue FFPE LV, SW v4.0 |
| 08780404001: | Archive Plate Transfer, SW v3.0 |
| 08780412001: | PCR Set up with Mixing, SW v3.0 |
| 08838275001: | PCR Set up without Mixing, SW v3.0 |
| 09290192001: | Sample Transfer, SW v4.0 |
| 08780447001: | Instrument Check, SW v3.0 |