EC Declaration of Conformity

EC Declaration of Conformity for In-vitro Diagnostic Products

The conformity is declared according to European IVD Regulation 2017/746 Annex IX chapter I, based on a full quality management system according to EN ISO 13485:2016 + AC:2016.

Name of manufacturer	MACHEREY-NAGEL GmbH & Co. KG
Address:	Valencienner Str. 11 D - 52355 Düren Germany
Single Registration number (SRN)	DE-MF-000005636

Name of product	**Reference numbers**
NucleoSpin Dx Virus	740895

Intended purpose:

The NucleoSpin® Dx Virus kit is a generic system for the isolation and purification of viral nucleic acids from human serum or plasma samples for subsequent *in-vitro* diagnostic purposes. The kit can be used with fresh and frozen human serum and plasma, stabilized with either EDTA or citrate from common blood collection systems. The kit is designed to be used with any downstream application employing enzymatic amplification and detection of RNA and DNA (e.g., RT-PCR, PCR).
The viral nucleic acids isolated and purified with NucleoSpin® Dx Virus can be used in qualitative applications (e.g., RT-PCR or PCR for blood screening) as well as in quantitative applications (e.g., detection of viral load by qPCR) employing diagnostic nucleic acid amplification techniques.

Any diagnostic results generated using nucleic acids isolated with the NucleoSpin® Dx Virus kit in conjunction with an *in-vitro* diagnostic assay should be interpreted with regard to additional clinical or laboratory findings. To minimize irregularities in diagnostic results, suitable controls for downstream applications (e.g., extraction controls, positive / negative controls) should be used.

The NucleoSpin® Dx Virus kit is intended to be used by professional users such as technicians and physicians experienced and trained in molecular biological techniques including experience with serum and plasma samples and viral nucleic acid isolation. The NucleoSpin® Dx Virus kit does not provide a diagnostic result. It is the sole responsibility of the user to use and validate the kit in conjunction with a downstream *in-vitro* diagnostic assay.

Besides human samples also fresh and frozen animal samples can readily be used together with the NucleoSpin® Dx Virus kit. Samples include, but are not limited to, serum, plasma, or swabs. It has to be noted that CE IVD labeling of the kit does not apply for animal samples but is limited to human diagnostic use only.

The NucleoSpin® Dx Virus kit is not suitable for self-testing or near-patient testing.

Risk class:	Class A
Notified body 0197:	TÜV Rheinland LGA Products GmbH Tillystr. 2. 90431 Nürnberg
Basic UDI-DI:	4046681151002VH
Applicable Common Specifications:	n.a.

We confirm that the product listed above is manufactured and QC controlled in compliance with the European IVD Regulation 2017/746. The manufacturer is exclusively responsible for the declaration of conformity.

Düren, 26.05.2022

ppa. Dr. Markus Meusel (QAM, Manager Reg. Affairs)