EU Declaration of Conformity

QIAamp® DSP Virus Spin Kit

REF 61704

Basic UDI-DI 4053228RQAVRS0000000002BX

Intended Purpose
The QIAamp DSP Virus Spin Kit is intended for manual or, when used in conjunction with the QIAcube® Connect MDx instrument, for automated isolation and purification of viral nucleic acids from human plasma and serum samples.
The QIAamp DSP Virus Spin Kit utilizes silica-membrane technology (QIAamp technology) for isolation and purification of viral nucleic acids from human plasma and serum samples.
The product is intended for in vitro diagnostic use and to be used by professional users, such as technicians and physicians who are trained in molecular biological techniques.

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SRN / Single Registration Number DE-MF-000004949

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above mentioned product(s) meet(s) the provisions of the following Regulation(s)/Directives:

Regulation EU 2017/746 on In vitro Diagnostic Medical Devices

RISK CLASS
☒ A ☐ B ☐ C ☐ D

CONFORMITY ASSESSMENT PROCEDURE
ANNEX II and III Conformity Assessment

On behalf of QIAGEN GmbH

[redacted]

Name

QIAGEN GmbH
Issued in

28 September 2022
Date

VP, Head of Global Regulatory Affairs
Function