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:
09040960190	**cobas**® BKV	761333602655BA

Intended Purpose:

cobas® BKV is an in vitro nucleic acid amplification test for the quantitation of BK virus (BKV) DNA in human EDTA plasma and urine stabilized in **cobas**® PCR Media.

In EDTA plasma, **cobas**® BKV is intended for use as an aid in the diagnosis and management of BKV in transplant patients. In patients undergoing monitoring of BKV in EDTA plasma, serial DNA measurements can be used to indicate the need for potential treatment changes and to assess viral response to treatment.

In urine stabilized in **cobas**® PCR Media, **cobas**® BKV is intended for use as an aid in the diagnosis and management of BKV in transplant patients.

The results from **cobas**® BKV must be interpreted within the context of all relevant clinical and laboratory findings.

cobas® BKV is not intended for use as a screening test for blood or blood products.

Risk Class and Classification Rule:	Class C per EU Regulation 2017/746, Annex VIII, Rule 3 (e)
Common Specifications:	No Common Specifications apply for the concerned device.
Name, Address and Identification number of the Notified Body:	BSI Group The Netherlands B.V. Notified Body Number: 2797 Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands

Conformity Assessment was established through the procedure described in Annex IX of EU Regulation 2017/746, including an assessment of the Technical Documentation as described in Annex IX, Chapter II. This declaration is supported by the following certificate(s):

EU Quality Management System Certificate: IVDR 732732 First Issued: 2021-04-29 Valid until: 2026-04-28

Conformity of the product with EU Regulation 2017/746 and other applicable EU legislation has been established.

On behalf of Roche Molecular Systems, Inc.

Place: Rotkreuz, Switzerland

Date: 22 August 2022

DocuSigned by:
Nathalie Pankiw
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Nathalie Pankiw
Network Lead Molecular Lab
Pre-Market Quality

Place: Pleasanton, CA

Date: 23 August 2022

DocuSigned by:
Rita Hoady
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Rita Hoady
Network Lead Molecular Lab
Director, Global Regulatory Affairs