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:
09040897190	**cobas**® CMV	761333601849BJ
09040919190	**cobas**® CMV Control Kit	761333601849BJ

Intended Purpose:

cobas® CMV is an *in vitro* nucleic acid amplification test for the quantitation of cytomegalovirus (CMV) DNA in human EDTA plasma.

cobas® CMV is intended for use as an aid in the diagnosis and management of CMV in solid organ transplant patients and in hematopoietic stem cell transplant patients. The test can be used in these populations to assess the need to initiate antiviral treatment. In patients receiving anti-CMV therapy, serial DNA measurements can be used to assess viral response to treatment.

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

Risk Class and Classification Rule: Class C per EU Regulation 2017/746, Annex VIII, Rule 3 (e)

Common Specifications:	Not applicable as no Common Specifications exist 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: Tucson, AZ

Date: 21-Dec-2021

DocuSigned by:
Jeff Boone
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Jeff Boone
Vice President, Quality Management

Place: Santa Clara, CA

Date: 20-Dec-2021

DocuSigned by:
Carolyn Glickman
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Carolyn Glickman
Director, Regulatory Affairs