Declaration of Conformity

as per Annex IV of the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 via BSI as the Notified Body (registration no. BSI-NL 2797)

Document No.:	**DOC-2023-01**
Manufacturer:	**Roche Molecular Systems, Inc.** **1080 US Highway 202 South** **Branchburg, NJ 08876** **USA**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**

Roche Molecular Systems, Inc. declares that the *in vitro* diagnostic medical device:

Product Name:	**cobas**® CMV *Quantitative nucleic acid test for use on the **cobas**® 6800/8800 Systems*
P/N:	09040897190: **cobas**® CMV – 192T 09040919190: **cobas**® CMV Control Kit
	Description: **cobas**® CMV is an *in vitro* nucleic acid amplification test for the quantitation of cytomegalovirus (CMV) DNA in human EDTA plasma. The complete Intended Use is contained in the **cobas**® CMV Package Insert.

Complies with the requirements of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

This declaration is supported by the following certificates:
EC Certificate – Full Quality Assurance: CE 707974, first issued 2019-03-26, valid until 2025-05-26

The Manufacturer agrees to develop, implement, and maintain a documented post-production monitoring process, including the notification of reportable events, under the European Medical Device Vigilance System Guidelines. As a legal manufacturer, Roche Molecular Systems, Inc., is solely responsible for the product. This declaration is issued under the sole responsibility of Roche Molecular Systems, Inc.

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Document No.: **DOC-2023-01**

Place: Rotkreuz, Switzerland

Date: 08 February 2023

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

Place: Pleasanton, CA

Date: 10 February 2023

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