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Declaration of Conformity

as per Annex III of the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998

Document No.: **DOC-2022-33**

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**® ADV/hMPV/EV-RV UC
cobas® ADV/hMPV/EV-RV UC Control Kit

P/N: 09555625190
09555595190

Description:
Qualitative nucleic acid test for use on the **cobas**® 6800/8800 Systems

The complete Intended Use is contained in the **cobas**® ADV/hMPV/EV-RV UC 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.

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 SolutionsMolecular Systems, Inc. is solely responsible for the product. This declaration is issued under the sole responsibility of Roche Sequencing Solutions, Inc.

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Declaration of Conformity

as per Annex III of the Directive 98/79/EC of the European Parliament
and the Council of 27 October 1998

Document No.: **DOC-2022-33**

Place: Tucson, AZ
Date: 12-May-2022

DocuSigned by:
Jeff Boone
D9C56B8025BB4D8...

Jeff Boone
VP, Quality Management
Roche Molecular Solutions

Place: Pleasanton, CA
Date: 13-May-2022

DocuSigned by:
Rita Hoady
36040CF34A65477...

Rita Hoady
Network Lead Molecular Lab
Director, Global Regulatory Affairs