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-2021-78**
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 omni** Utility Channel Reagent Kit
P/N:	09052011190

Description:
The **cobas omni** Utility Channel Reagent Kit provides the reagents and internal-control primers and probes necessary to utilize the open channel functionality of the **cobas**® 5800/6800/8800 Systems for the automated Polymerase Chain Reaction based Nucleic Acid Testing in order to develop tests for *in vitro* diagnostic use. The reagent kit is intended for use by trained professionals in the laboratory setting

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

Tucson, AZ

Date: 01-Dec-2021

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Vice President, Quality Management

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