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:
06997538190	**cobas omni** Lysis Reagent	761333602374AX
06997546190	**cobas omni** MGP Reagent	761333602374AX
06997511190	**cobas omni** Specimen Diluent	761333602374AX
06997503190	**cobas omni** Wash Reagent	761333602374AX

Intended Purpose: The **cobas omni** reagents are for use with the **cobas®** 5800/6800/8800 Systems.

The **cobas®** 5800/6800/8800 Systems support an automated and integrated workflow to run Polymerase Chain Reaction (PCR) based Nucleic Acid Testing (NAT). The **cobas®** 5800/6800/8800 Systems combine Instrumentation, Consumables, Reagents and Data Management to provide an efficient workflow from sample processing to result interpretation.

Risk Class and Classification Rule: Class A, as per EU Regulation 2017/746, Annex VIII, Rule 5 (a)

Common Specifications: Not applicable as no Common Specifications exist for the concerned device.

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