



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) **US-MF-000018066**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH**
Sandhofer Strasse 116
68305 Mannheim
Germany

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

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:

A handwritten signature in black ink that reads "Jeff Boone".

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Jeff Boone

Vice President, Quality Management

Place: Santa Clara, CA

Date: 20-Dec-2021

DocuSigned by:

A handwritten signature in black ink that reads "Carolyn Glickman".

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Carolyn Glickman

Director, Regulatory Affairs