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:
09052011190	**cobas omni** Utility Channel Reagent Kit	761333602416AN

Intended Purpose:	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.
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: 12-Jan-2022

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Jeff Boone
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Jeff Boone
Vice President, Quality Management

Place: Pleasanton, CA

Date: 12-Jan-2022

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Rita Hoady
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Director, Global Regulatory Affairs