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:
08413975001	**cobas omni** Processing Plate 24	761333602373AV
08413983001	**cobas omni** Liquid Waste Plate 24	761333602373AV
08499853001	**cobas omni** Amplification Plate 24	761333602373AV

Intended Purpose: The **cobas omni** Amplification Plate 24, Processing Plate 24 and Liquid Waste Plate 24 are single-use consumables intended for use with the **cobas®** 5800 System.

The **cobas®** 5800 System supports an automated and integrated workflow to run Polymerase Chain Reaction (PCR) based Nucleic Acid Testing (NAT) for use by trained professionals in laboratory settings. The **cobas®** 5800 System combines the functionalities of instrumentation, consumables, reagents and data management to provide an efficient workflow from sample processing to result interpretation.

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Date: 2023.12.21 15:37:52 EET
Reason: MoldSign Signature
Location: Moldova

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