



## 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:
08413975001	<b>cobas omni</b> Processing Plate 24	761333602373AV
08413983001	<b>cobas omni</b> Liquid Waste Plate 24	761333602373AV
08499853001	<b>cobas omni</b> 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.



**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