



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	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.



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