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:
09040773190	**cobas**® HBV/HCV/HIV-1 Control Kit	7613336000858BC

Intended Purpose:	**cobas**® HBV/HCV/HIV-1 Control Kit is intended for use as a positive run/batch control on the **cobas**® 5800/6800/8800 Systems with the **cobas**® HBV, **cobas**® HCV, and **cobas**® HIV-1 tests.
Risk Class and Classification Rule:	Class D, as per EU Regulation 2017/746, Annex VIII, Rule 1
Common Specifications:	The Commission Implementing Regulation (EU) 2022/1107 is applicable for this product.
Name, Address and Identification number of the Notified Body:	BSI Group The Netherlands B.V. Notified Body Number: 2797 Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands

Conformity Assessment was established through the procedure described in Annex IX of EU Regulation 2017/746, including an assessment of the Technical Documentation as described in Annex IX, Chapter II. This declaration is supported by the following certificate(s):

EU Quality Management System Certificate:
IVDR 732732 First Issued: 2021-04-29, Valid until 2026-04-28

EU Technical Documentation Assessment certificate:
IVDR 732826 First Issued: 2024-09-05, Valid until: 2029-09-04

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: Branchburg, NJ

Date: 13 November 2024

Signed by:
Amy Muska
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Amy Muska
Network Lead
Site Head Branchburg & Santa Clara

Place: Pleasanton, CA

Date: 15 November 2024

DocuSigned by:
Rita Hoady
36040CF34A6547...

Rita Hoady
Network Lead Molecular Lab
Director, Global Regulatory Affairs