



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:
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):

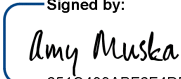
EU Quality Management System Certificate:
IVDR 732732 First Issued: 2021-04-29, Valid until 2026-04-28

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
13 November 2024
Date:

Signed by:

651C488ABE6E4DE...
Amy Muska
Network Lead
Site Head Branchburg & Santa Clara

Place: Pleasanton, CA
15 November 2024
Date:

DocuSigned by:

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Rita Hoady
Network Lead Molecular Lab
Director, Global Regulatory Affairs