



# 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	<b>cobas®</b> 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):

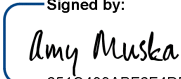
EU Quality Management System Certificate:  
IVDR 732732 First Issued: 2021-04-29, Valid until 2026-04-28

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:  
  
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**Amy Muska**  
Network Lead  
Site Head Branchburg & Santa Clara

Place: Pleasanton, CA  
15 November 2024  
Date:

DocuSigned by:  
  
36040CF34A85477...  
**Rita Hoady**  
Network Lead Molecular Lab  
Director, Global Regulatory Affairs