



EU Declaration of Conformity

as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

Manufacturer: Roche Molecular Systems, Inc.
Address: 1080 US Highway 202 South
 Branchburg, New Jersey 08876
Single Registration Number: US-MF-000018066

Authorized Representative: Roche Diagnostics GmbH
Address: Sandhofer Strasse 116
 68305 Mannheim
 Germany
SingleRegistrationNumber DE-AR-000006262

Roche Molecular Systems, Inc. declares, under the sole responsibility, that the product/the product line

Product Name	Cat. No. / REF	Basic UDI-DI
cobas® HBV	09040820190	761333600845B3

Intended Purpose:

cobas® HBV is an in vitro nucleic acid amplification test for the quantitation of hepatitis B virus (HBV) DNA in human EDTA plasma or serum of HBV-infected individuals.
 This test is intended for use as an aid in the management of patients with chronic HBV infection undergoing anti-viral therapy. The test can be used to measure HBV DNA levels at baseline and during treatment to aid in assessing response to treatment. The results from **cobas® HBV** must be interpreted within the context of all relevant clinical and laboratory findings.

Risk Class: A B C D

Conformity Route:

- Self-Declaration of Conformity (Class A)
- Self-Declaration of Conformity after Notified Body involvement for sterile manufacturing conditions acc. Art. 48 (10) (Class A sterile)
- Technical Documentation Assessment Class B/C – Annex IX
- Technical Documentation Assessment Class D – Annex IX
- Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX
- Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX
- Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX

Certificates: EU QM Certificate No.: IVDR 732732



EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): IVDR 732821

Other:

Common Specifications: DH-270-336

Notified Body (NB) Name: BSI Group The Netherlands B.V.

NB Address: Say Building, John M. Keynesplein 9
1066 EP Amsterdam
Netherlands

NB Ident. No.: 2797

to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Branchburg, NJ, 17. April 2026

Roche Molecular Systems, Inc.

ppa./on behalf of the company

Pleasanton, CA, 17 April 2026

Roche Molecular Systems, Inc.

ppa./on behalf of the company

Signiert von:

Sabrina Sommer
6BF7647AFD3E45B...

Sabrina Sommer
Network Lead Quality Site Head
Branchburg, Santa Clara & Pleasanton

DocuSigned by:

Rita Hoady
36040CF34A65477...

Rita Hoady
Network Lead
Global Head of Regulatory Affairs, Molecular Labs

Contact address:

1080 US Highway 202 South
Branchburg, New Jersey 08876
USA