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, NJ 08876 USA
Single Registration Number:	US-MF-000018066
Authorized Representative:	Roche Diagnostics GmbH
Address:	Sandhofer Strasse 116 68305 Mannheim Germany
Single Registration Number:	DE-AR-000006262

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

Product Name	Cat. No.	Basic UDI-DI
cobas® HCV	09040765190	761333600847B7

Intended Purpose:

cobas® HCV is an in vitro nucleic acid amplification test for both the detection and quantitation of hepatitis C (HCV) RNA, genotypes 1 to 6, in human EDTA plasma or serum or from a **cobas**® Plasma Separation Card (PSC) dried plasma spot of HCV-infected individuals.
cobas® HCV is intended for use as an aid in the diagnosis of HCV infection in the following populations: individuals with antibody evidence of HCV with evidence of liver disease, individuals suspected to be actively infected with HCV antibody evidence, and individuals at risk for HCV infection with antibodies to HCV. Detection of HCV RNA indicates that the virus is replicating and therefore is evidence of active infection.
The test is intended for use in the management of patients with chronic HCV in conjunction with clinical and laboratory markers of infection. The test can be used to predict the probability of sustained virologic response (SVR) early during a course of antiviral therapy, and to assess viral response to antiviral treatment (response guided therapy) as measured by changes of HCV RNA levels in serum or EDTA plasma. The results must be interpreted within the context of all relevant clinical and laboratory findings. **cobas**® PSC dried plasma spots may be used in accordance with clinical practice guidelines and the assay's performance characteristics.

Intended Use:

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 First Issued 29 April 2021, Expiry 28 April 2026 ☒ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): IVDR 732822 First Issued 15 May 2024, Expiry 14 May 2029
Other:	☒ Common Specifications: Commission Implementing Regulation (EU) 2022/1107
Notified Body (NB) Name:	BSI Group The Netherlands B.V.
NB Address:	Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands
NB Identification. No.:	Notified Body Number: 2797

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

Branchburg, NJ
12 December 2024

Roche Molecular Systems, Inc.

ppa./*on behalf of the company*

Signed by:
Amy Muska
651C488ABE6E4DE...

Amy Muska
Network Lead
Site Head Branchburg & Santa Clara

Pleasanton, CA
11 December 2024

Roche Molecular Systems, Inc.

ppa./*on behalf of the company*

DocuSigned by:
Rita Hoady
36040CF34A65477...

Rita Hoady
Network Lead Molecular Lab
Director, Global Regulatory Affairs

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