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® MPX - 192	09288538190	761333602493B8
cobas® MPX - 480	09040862190	761333600540AA
cobas® MPX Control Kit	09040846190	761333600541AC
cobas® NHP Negative Control Kit	09051554190	761333600542AE

Intended Purpose/ Intended Use:

The **cobas**® MPX test for use on the **cobas**® 5800/6800/8800 systems is a qualitative in vitro test for the direct detection of Human Immunodeficiency Virus Type 1 (HIV-1) Group M RNA, HIV-1 Group O RNA, Human Immunodeficiency Virus Type 2 (HIV-2) RNA, Hepatitis C Virus (HCV) RNA, and Hepatitis B Virus (HBV) DNA in human plasma and serum.

This test is intended for use to screen donor samples for HIV-1 Group M RNA, HIV-1 Group O RNA, HIV-2 RNA, HCV RNA, and HBV DNA in plasma and serum samples from individual human donors, including donors of whole blood, blood components, and other living donors. This test is also intended for use to screen organ and tissue donors when donor samples are obtained while the donor's heart is still beating and in testing of cadaveric (non-heart beating) donors. Plasma and serum from all donors may be screened as individual samples. For donations of whole blood and blood components, plasma

and serum samples may be tested individually or plasma may be tested in pools comprised of aliquots of individual samples. For donations from cadaveric (non-heart beating) organ and tissue donors, samples may only be screened as individual sample.

For an individual sample, results are simultaneously detected and discriminated for HIV, HCV, and HBV.

The **cobas**® MPX test can be considered a supplemental test that confirms HIV infection for samples that are repeatedly reactive on a CE-IVD test for antibodies to HIV and reactive on the **cobas**® MPX test.

The **cobas**® MPX test can be considered a supplemental test that confirms HCV infection for samples that are repeatedly reactive on a CE-IVD test for antibodies to HCV and reactive on the **cobas**® MPX test.

The **cobas**® MPX test can be considered a supplemental test that confirms HBV infection for samples that are repeatedly reactive on a CE-IVD test for Hepatitis B surface antigen and reactive on the **cobas**® MPX test.

This test may also be used as an aid in the diagnosis of HIV, HCV, or HBV in samples collected from individuals suspected of infection with these viruses by their healthcare provider or to screen individuals whose infection status for HIV, HCV or HBV is unknown.

Intended Purpose/ 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 issued 2021-04-29, valid until 2026-04-28 ☒ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): IVDR 732739 issued 2023-10-31, valid until 2028-10-30
Other:	☒ Common Specifications: The Commission Implementing Regulation (EU) 2022/1107 Annex I, III, V and VI are applicable for this product.
Notified Body (NB) Name:	BSI Group The Netherlands B.V.
NB Address:	Say Building, John M. Keynesplein 9, 1066EP 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, USA
28 April 2025

Roche Molecular Systems, Inc.

on behalf of the company

DocuSigned by:
E185EF14136A458...

Timothy Blair
Network Lead
Quality Site Head Branchburg, Santa Clara & Pleasanton

Pleasanton, USA
29 April 2025

Roche Molecular Systems, Inc.

on behalf of the company

DocuSigned by:
Rita Hoady
36040CF34A65477...

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

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