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) Manufacturer:	**US-MF-000018066**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

This declaration is issued under the sole responsibility of Roche Molecular Systems, Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
09288538190	**cobas**® MPX – 192	761333602493B8
09040862190	**cobas**® MPX – 480	761333600540AA
09040846190	**cobas**® MPX Control Kit	761333600541AC
09051554190	**cobas**® NHP Negative Control Kit	761333600542AE

Intended Purpose:

The **cobas**® MPX test, for use on **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 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 is not intended for use as an aid in diagnosis of infection with HIV, HCV, or HBV.
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: IVDR732732
First Issued: 2021-04-29 Valid until: 2026-04-28
EU Technical Documentation Assessment certificate: IVDR732739
First Issued: 2023-10-31 Valid until: 2028-10-30

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: Rotkreuz, Switzerland

Date: 29 November 2023

DocuSigned by:
Nathalie Pankiw
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Nathalie Pankiw
Network Lead Molecular Lab
Pre-Market Quality

Place: Pleasanton, CA

Date: 29 November 2023

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