Declaration of Conformity

as per Annex IV of the Directive 98/79/EC of the European Parliament and the Council of 27 October 1998 via BSI as the Notified Body (registration no. BSI-NL 2797)

Document No.:	**DOC-2022-11**
Manufacturer:	**Roche Molecular Systems, Inc.** **1080 US Highway 202 South** **Branchburg, NJ 08876** **USA**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
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**

Roche Molecular Systems, Inc. declares that the *in vitro* diagnostic medical device:

Product Name:	**cobas**® MPX *For use on the **cobas**® 5800/6800/8800 Systems*
P/N:	09040862190: **cobas**® MPX – 480 09040846190: **cobas**® MPX Control Kit
	Description: 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 (HBV) DNA in human plasma and serum. The complete Intended Use is contained in the **cobas**® MPX Package Insert.

Complies with the requirements of the Directive 98/79/EC of the European Parliament and of the Council of 27 October 1998 on *in vitro* diagnostic medical devices.

This declaration is supported by the following certificates:
EC Certificate – Full Quality Assurance: CE 707974, first issued 2019-03-26, valid until 2025-05-26
EC Design-Examination Certificate: CE 708021, first issued 2019-03-26, valid until 2025-05-26

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The Manufacturer agrees to develop, implement, and maintain a documented post-production monitoring process, including the notification of reportable events, under the European Medical Device Vigilance System Guidelines. As a legal manufacturer, Roche Molecular Systems, Inc., is solely responsible for the product. This declaration is issued under the sole responsibility of Roche Molecular Systems, Inc.

Place: Tucson, AZ

Date: 19-May-2022

Jeff Boone

Jeff Boone
Vice President, Quality Management

Place: Pleasanton, CA

Date: 17-May-2022

Rita Hoady

Rita Hoady
Network Lead Molecular Lab
Director, Global Regulatory Affairs