



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



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**

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

Place: Pleasanton, CA

Date: 17-May-2022

A handwritten signature in black ink that reads "Jeff Boone".

Jeff Boone
Vice President, Quality Management

A handwritten signature in black ink that reads "Rita Hoady".

Rita Hoady
Network Lead Molecular Lab
Director, Global Regulatory Affairs