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-2021-44**
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**

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

Product Name: COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, v2.0

P/N: 04894570190

Description:

The COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, version 2.0 (v2.0) is an *in vitro* nucleic acid amplification test for the quantitation of Hepatitis B Virus (HBV) DNA in human plasma and serum, using the COBAS® AmpliPrep Instrument for automated specimen processing and the COBAS® TaqMan® Analyzer or COBAS® TaqMan® 48 Analyzer for automated amplification and detection.

The complete Intended Use is contained in the COBAS® AmpliPrep/COBAS® TaqMan® HBV Test, version 2.0 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 2024-03-25
EC Design-Examination Certificate: CE 709234, first issued 2019-03-26, valid until 2023-11-16

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.

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-2021-44**

Place: Tucson, AZ

Date: 30-Jun-2021

DocuSigned by:
Jeff Boone
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Jeff Boone
VP, Quality Management
Roche Molecular Solutions

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-2021-43**
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**

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

Product Name:	COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test, v2.0
P/N:	05532264190

Description:
The COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test, v2.0 is an *in vitro* nucleic acid amplification test for the quantitation of Hepatitis C Virus (HCV) RNA genotypes 1 to 6 in human EDTA plasma or serum using the COBAS® AmpliPrep Instrument for automated specimen processing and the COBAS® TaqMan® Analyzer or the COBAS® TaqMan® 48 Analyzer for automated amplification and detection.

The complete Intended Use is contained in the COBAS® AmpliPrep/COBAS® TaqMan® HCV Quantitative Test, v2.0 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 2024-03-25
EC Design-Examination Certificate: CE 709237, first issued 2019-05-02, valid until 2024-05-26

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.

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-2021-43**

Place: Tucson, AZ

Date: 30-Jun-2021

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VP, Quality Management
Roche Molecular Solutions