



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-2022-09**

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[®] HBV**
*Quantitative nucleic acid test for use on the **cobas[®] 5800/6800/8800 Systems***

P/N: 09040820190

Description:

cobas[®] HBV is an *in vitro* nucleic acid amplification test for the quantitation of hepatitis B virus (HBV) DNA in human EDTA plasma or serum of HBV-infected individuals.

The complete Intended Use is contained in the **cobas[®] HBV** 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 708019, first issued 2019-03-26, valid until 2025-05-26

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.



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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