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-2022-23**
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**® HIV-1/HIV-2 Qualitative *Nucleic acid test for use on the **cobas**® 5800/6800/8800 Systems*
P/N:	09040528190: **cobas**® HIV-1/HIV-2 Qualitative – 192T 09040536190: **cobas**® HIV-1/HIV-2 Qualitative Control Kit
	Description: **cobas**® HIV-1/HIV-2 Qualitative nucleic acid test for use on the **cobas**® 5800/6800/8800 Systems is an in vitro nucleic acid amplification test for the qualitative detection and differentiation of human immunodeficiency virus (HIV) type 1 (HIV-1) and type 2 (HIV-2) in human serum, plasma, and dried blood spots (DBS). The complete Intended Use is contained in the **cobas**® HIV-1/HIV-2 Qualitative 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 709232, first issued 2019-05-02, 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