EU Declaration of Conformity

as per Annex IV of the Regulation EU 2017/746 on in-vitro diagnostic medical devices

Manufacturer:	Roche Molecular Systems, Inc.
Address:	1080 US Highway 202 South Branchburg, NJ 08876 USA
Single Registration Number:	US-MF-000018066
Authorized Representative:	Roche Diagnostics GmbH
Address:	Sandhofer Strasse 116 68305 Mannheim Germany
Single Registration Number:	DE-AR-000006262

Roche Diagnostics GmbH declares, under the sole responsibility, that the product/the product line

Product Name	Cat. No.	Basic UDI-DI
cobas® WNV 480T	09040927190	761333600866BB
cobas® WNV 192T	09171142190	761333602494BA
cobas® WNV Control Kit	09040935190	761333600867BD

Intended Purpose:

The **cobas®** WNV test for use on **cobas®** 5800/6800/8800 systems is a qualitative in vitro test for the direct detection of West Nile Virus (WNV) RNA in human plasma.

This test is intended for use to screen donor samples for WNV RNA in plasma samples from individual human donors, including donors of whole blood and blood components, as well as other living donors. This test is also intended for use to screen organ and tissue donors when donor samples are obtained while the donor's heart is still beating and for testing of cadaveric (non-heart beating) donors.

This test is not intended for use on samples of cord blood.

Plasma from all donors may be screened as individual samples. For donations of whole blood and blood components, plasma samples may be tested individually or may be tested in pools comprised of aliquots of individual samples. For donations from cadaveric (non-heart beating) organ and tissue donors, samples may only be screened as individual sample.

This test may also be used as an aid in diagnosis of WNV in samples collected from individuals suspected of infection with WNV by their healthcare provider.

When used as an aid in diagnosis, plasma samples should only be tested individually.

Intended Use:

Risk Class:	☐ A ☐ B ☐ C ☒ D
Conformity Route:	☐ Self-Declaration of Conformity (Class A)
	☐ Self-Declaration of Conformity after Notified Body involvement for sterile manufacturing conditions acc. Art. 48 (10) (Class A sterile)
	☐ Technical Documentation Assessment Class B/C – Annex IX
	☒ Technical Documentation Assessment Class D – Annex IX
	☐ Technical Documentation Assessment Class B/C/D for Self-Testing – Annex IX
	☐ Technical Documentation Assessment Class B/C/D for Near-Patient Testing – Annex IX
	☐ Technical Documentation Assessment Class C/D for Companion Diagnostics – Annex IX
Certificates:	☒ EU QM Certificate No.: IVDR 732732 First Issued: 2021-04-29 Valid until: 2026-04-28
	☒ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): IVDR 732831 Issued: 2023-05-31 Valid until: 2028-05-30.
Other:	☐ Common Specifications: The Commission Implementing Regulation (EU) 2022/1107 is not applicable for this product.
Notified Body (NB) Name:	BSI Group The Netherlands B.V.
NB Address:	Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, Netherlands
NB Ident. No.:	2797

to which this declaration relates fulfils the requirements of Regulation EU 2017/746 on in-vitro diagnostic medical devices.

Branchburg, USA
03 March 2025

Roche Molecular Solutions, Inc.

on behalf of the company

DocuSigned by:
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Timothy Blair
Network Lead
Quality Site Head Branchburg, Santa Clara & Pleasanton

Contact address: 1080 US Highway 202 South
Branchburg, New Jersey
08876

Pleasanton, USA
27 February 2025

Roche Molecular Solutions, Inc.

on behalf of the company

DocuSigned by:
Rita Hoady
36040CF34A65477...

Rita Hoady
Network Lead
Global Head of Regulatory Affairs, Molecular Lab