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 Molecular Systems, Inc. declares, under the sole responsibility, that the product/the product line

Product Name	Cat. No.	Basic UDI-DI
cobas® Malaria - 192	09352511190	761333602917BH
cobas® Malaria Control Kit	09352520190	761333602918BK

Intended Purpose:

The **cobas**® Malaria test for use on the **cobas**® 5800/6800/8800 systems (**cobas**® Malaria) is a qualitative in vitro nucleic acid screening test for the direct detection of Plasmodium (P. falciparum, P. malariae, P. vivax, P. ovale and P. knowlesi) DNA and RNA in whole blood samples from individual human donors, including donors of whole blood and blood components, as well as other living donors. It is also intended for use in testing whole blood samples to screen organ and tissue donors when samples are obtained while the donor's heart is still beating.

Whole blood samples from all donors may be screened as individual samples. For donations of whole blood and blood components, whole blood samples may be tested individually or in pools comprised of aliquots of individual samples.

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

This test is not intended for use on cadaveric samples.

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

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.: IVDR732732
	☒ EU Technical Documentation Assessment Certificate No. (Class D, Near-Patient Testing, Self-Testing and Companion Diagnostics): IVDR791536
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, 1066EP 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

25 July 2025

Roche Molecular Systems, 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, NJ 08876
USA

Pleasanton, USA

24 July 2025

Roche Molecular Systems, Inc.

on behalf of the company

DocuSigned by:
Rita Hoady
36040CF34A65477...

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