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® Babesia - 480	09040692190	761333602097AU
cobas® Babesia Control Kit	09040706190	7613336021209W

Intended Purpose/Intended Use:

The **cobas**® Babesia test for use on the **cobas**® 5800/6800/8800 systems is a qualitative in vitro nucleic acid screening test for the direct detection of Babesia (B. microti, B, duncani, B. divergens, and B. venatorum) DNA and RNA in whole blood samples from individual human donors, including donors of whole blood and blood components, and 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. Whole blood samples from all donors may be screened as individual samples or in pools comprised of aliquots of individual samples.

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

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

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

This test is not intended for use on cadaveric blood specimens.

Intended Purpose/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 732837
	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
11 April 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

Pleasanton, USA
09 April 2025

Roche Molecular Systems, Inc.

on behalf of the company

Signed by:
Nobuko Nakajima
3FD52E3D2EAE420...

Nobuko Nakajima
Network Lead
Global Head of Regulatory Affairs, Near Patient Care

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