



EU Declaration of Conformity

In accordance with Annex IV of EU Regulation 2017/746 of the European Parliament and of the Council of 5 April 2017 on *in vitro* diagnostic medical devices.

Manufacturer: **Roche Molecular Systems, Inc.
1080 US Highway 202 South
Branchburg, NJ 08876
USA**

Single Registration Number (SRN) **US-MF-000018066**
Manufacturer:

Authorized Representative: **Roche Diagnostics GmbH
Sandhofer Strasse 116
68305 Mannheim
Germany**

Single Registration Number (SRN) **DE-AR-000006262**
Authorized Representative:

This declaration is issued under the sole responsibility of Roche Molecular Systems, Inc.

Product Information

Part Number:	Product Name:	Basic UDI-DI:
09040803190	cobas [®] HIV-1	761333600853B2

Intended Purpose: **cobas**[®] HIV-1 is an *in vitro* nucleic acid amplification test for the quantitation of human immunodeficiency virus type 1 (HIV-1) in EDTA plasma or from a **cobas**[®] Plasma Separation Card (PSC) dried plasma spot of HIV-1-infected individuals.

This test is intended for use in conjunction with clinical presentation and other laboratory markers for the clinical management of HIV-1-infected patients. This test can be used for confirmation of HIV-1 infection in antibody reactive individuals and to assess patient prognosis by measuring the baseline HIV-1 level or to monitor the effects of antiretroviral therapy by measuring changes in HIV-1 RNA levels during the course of antiretroviral treatment.

The complete Intended Use is contained in the **cobas**[®] HIV-1 Package Insert.



Risk Class and Classification Rule: Class D per EU Regulation 2017/746, Annex VIII, Rule 1

Common Specifications: Commission Implementing Regulation (EU) 2022/1107 of 4 July 2022 laying down common specifications for certain class D in vitro diagnostic medical devices in accordance with Regulation (EU) 2017/746 of the European Parliament and of the Council

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

Conformity Assessment was established through the procedure described in Annex IX of EU Regulation 2017/746, including an assessment of the Technical Documentation as described in Annex IX, Chapter II. This declaration is supported by the following certificate(s):

EU Quality Management System Certificate IVDR 732732:
Issued 2021-04-09
Valid until 2026-04-28

EU Technical Documentation Assessment certificate IVDR 732824:
Issued 2024-02-12
Valid until 2029-02-11.

Conformity of the product with EU Regulation 2017/746 and other applicable EU legislation has been established.

On behalf of Roche Molecular Systems, Inc.

Place: Branchburg, NJ

Place: Pleasanton, CA

Date: 06 December 2024

Date: 05 December 2024

Signed by:

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