



# EU Declaration of Conformity

In accordance with 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:
07341920190	<b>cobas® liat</b> analyzer	761333602043A5
<i>Including</i>		
09408355001	<b>cobas® liat</b> cleaning tool kit	

**Intended Purpose:** The **cobas® liat** analyzer is an automated nucleic acid test instrument, that when used together with **cobas® Liat®** assay tubes to perform *in vitro* diagnostic tests, is referred to as the **cobas® Liat®** System. In conjunction with a **cobas® Liat®** assay tube, the instrument performs reagent preparation, target enrichment, inhibitor removal, nucleic acid extraction, polymerase chain reaction (PCR) amplification, real-time detection, and result interpretation to automate the detection or quantification of nucleic acid targets in a biological sample.

**Risk Class and Classification Rule:** Class A, as per EU Regulation 2017/746, Annex VIII, Rule 5 (b)

**Common Specifications:** Not applicable as no Common Specifications exist for the concerned device.



Conformity of the product with EU Regulation 2017/746 and the following EU legislation, which also require an EU Declaration of Conformity, and other applicable EU legislation, has been established.

- Directive 2011/65/EU of the European Parliament and of the Council of 8 June 2011 on the restriction of the use of certain hazardous substances in electrical and electronic equipment (RoHS).

Starting with Serial no.: 17000

On behalf of Roche Molecular Systems, Inc.

Place: Rotkreuz, Switzerland

Date: 11 October 2023

DocuSigned by:

*Nathalie Pankiw*

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**Nathalie Pankiw**

Network Lead Molecular Lab  
Pre-Market Quality

Place: Pleasanton, CA, USA

Date: 11 October 2023

DocuSigned by:

*Nobuko Nakajima*

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**Nobuko Nakajima**

Network Lead  
Global Head of Regulatory Affairs, Point of Care