



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:
09541713001	LightCycler® PRO, 96	761333603111A4
09582487001	LightCycler® PRO, 384	761333603112A6

Intended Purpose: The LightCycler® PRO System combines the functionalities of instrumentation, consumables, reagents, and data management to support a semi-automated workflow for polymerase chain reaction based nucleic acid testing. For use by trained professionals in laboratory settings.

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 for the concerned device are available.

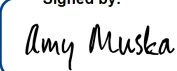


Conformity of the product with EU Regulation 2017/746 and the following EU legislation, which also requires an EU Declaration of Conformity, and other applicable EU legislation, has been established.

- 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).


On behalf of Roche Molecular Systems, Inc.

Place: Branchburg, NJ
05 September 2024
Date:

Signed by:

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Amy Muska

Network Lead
Site Head Branchburg & Santa Clara

Place: Pleasanton, CA
09 September 2024
Date:

DocuSigned by:

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Rita Hoady

Network Lead Molecular Lab
Director, Global Regulatory Affairs