

# EU Technical Documentation Assessment Certificate

Regulation (EU) 2017/746, Annex IX Chapter II

## IVDR 732757 R000

**Manufacturer:** Roche Molecular Systems, Inc.

**Address:**

1080 US Highway 202 South  
Branchburg  
New Jersey  
08876  
USA

**Single Registration Number:** US-MF-000018066

**EU Authorised Representative:** Roche Diagnostics GmbH

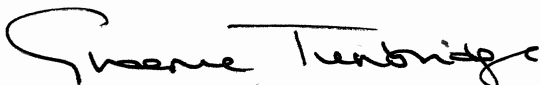
**Address:**

Sandhofer Str. 116  
Mannheim  
68305  
Germany

**Scope:** See attached **Device Schedule**

On the basis of our assessment of the technical documentation in accordance with Regulation (EU) 2017/746, Annex IX Chapter II, the technical documentation meets the requirements of the Regulation. For the placing on the market of these devices an additional Annex IX Chapter I and III certificate is required.

For and on behalf of BSI, a Notified Body for the above Regulation (Notified Body Number 2797):



Graeme Tunbridge, Senior Vice President Global Regulatory & Quality

First Issue Date: **2021-11-17**

Current Issue Date: **2025-06-17**

Starting Validity Date: **2025-06-17**

Expiry Date: **2026-11-16**

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### Device Schedule:

**Risk Classification:** Class B near-patient devices

Device Name	Model	Type (Codes as per (EU) 2017/2185)	Intended purpose (as per the IFU)	Basic UDI-DI
<b>cobas®</b> Strep A Nucleic acid test for use on the <b>cobas®</b> Liat® System	07341911190	IVR 0503	The <b>cobas®</b> Strep A nucleic acid test for use on the <b>cobas®</b> Liat® System ( <b>cobas®</b> Strep A) is a qualitative in vitro diagnostic test for the detection of Streptococcus pyogenes (Group A β-hemolytic Streptococcus, Strep A) in throat swab specimens from patients with signs and symptoms of pharyngitis. The <b>cobas®</b> Strep A assay utilizes nucleic acid purification and polymerase chain reaction (PCR) technology to detect Streptococcus pyogenes by targeting a segment of the Streptococcus pyogenes genome. The <b>cobas®</b> Strep A nucleic acid test for use on the <b>cobas®</b> Liat® System is intended for use by health professionals or trained operators who are proficient in using the <b>cobas®</b> Liat® System in Near Patient Testing, Point of Care (POC), or clinical laboratory settings.	761333601256AH
<b>cobas®</b> Strep A Quality Control Kit for use on the <b>cobas®</b> Liat® System	07402678190	IVR 0503	External Controls for use with the <b>cobas®</b> Liat® Strep A assay nucleic acid test for use on the <b>cobas®</b> Liat® System (07341911190).	761333601255AF

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Validity of this certificate is conditional on the Manufacturer's quality system being maintained to the requirements of the Regulation as demonstrated through the required surveillance activities of the Notified Body.  
This certificate was issued electronically and is bound by the conditions of the contract.

NB Contact: BSI Group The Netherlands B.V., Say Building, John M. Keynesplein 9, 1066 EP, Amsterdam, Netherlands. Tel: + 31 (0) 20 346 07 80  
Corporate Contact: BSI Group Assurance Limited, registered in England under number 05435540 at 389 Chiswick High Road, London, W4 4AL, UK.  
A Member of the BSI Group of Companies.

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### Certificate History

(References to applicable Common Specifications, Harmonized Standards complied with, and the relevant test and audit reports that support any of the below certificate changes may be requested from [Certificate.Verification@bsigroup.com](mailto:Certificate.Verification@bsigroup.com))

Date	Reference Number	Action
2021-11-17	3257669	Issued
2024-05-31	30096164	Amended – Addition of sodium azide, additional filtration step of the MMXR2 bulk to 0.2 microns, and replacement of surfactant NP-40 with a similar surfactant, Tween-20
Current	30446042	Amended – Correction to the basic UDI-DI for the <b>cobas®</b> Strep A Nucleic acid test for use on the <b>cobas®</b> Liat® System Kit M/N 0734191190. Amendment of the Intended Use for clarification with regards to the intended user (no change to actual intended use or user of the device)

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