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) Manufacturer:	**US-MF-000018066**
Authorized Representative:	**Roche Diagnostics GmbH** **Sandhofer Strasse 116** **68305 Mannheim** **Germany**
Single Registration Number (SRN) Authorized Representative:	**DE-AR-000006262**

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

Product Information

Part Number:	Product Name:	Basic UDI-DI:
08160104190	**cobas**® Influenza A/B & RSV nucleic acid test for use on the **cobas**® Liat® System	761333601252A9
07402686190	**cobas**® Influenza A/B & RSV Quality Control Kit for use on the **cobas**® Liat® System	761333601251A7

Intended Purpose:

The **cobas**® Influenza A/B & RSV Nucleic acid test for use on the **cobas**® Liat® System (**cobas**® Influenza A/B & RSV) is an automated multiplex real-time RT-PCR assay for the rapid *in vitro* qualitative detection and discrimination of Influenza A virus, Influenza B virus and respiratory syncytial virus (RSV) RNA in nasopharyngeal swab specimens from patients with signs and symptoms of respiratory infection in conjunction with clinical and epidemiological risk factors.

The complete Intended Use is contained in the **cobas**® Influenza A/B & RSV Package Insert.

Risk Class and Classification Rule: Class B per EU Regulation 2017/746, Annex VIII, Rule 4b & Rule 6

Common Specifications: At this time, no Common Specifications for the concerned device are available.

Name, Address and Identification number of the Notified Body:	BSI Group The Netherlands B.V., 2797

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 2021-04-29 Valid until 2026-04-28
EU Technical Documentation Assessment certificate: IVDR 732839 Issued 2021-11-17 Valid until 2026-11-16

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: Tucson, AZ	Place: Pleasanton, CA
Date: 09-Mar-2022	Date: 09-Mar-2022
Jeff Boone	Rita Hoady
Jeff Boone Vice President, Quality Management	**Rita Hoady** Network Lead Molecular Lab Director, Global Regulatory Affairs