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:
07460155190 09040544190	**cobas**® HPV	761333600556AR
07460171190 09040552190	**cobas**® HPV Positive Control Kit	761333600556AR

Intended Purpose:

cobas® HPV for use on the **cobas**® 5800/6800/8800 Systems (**cobas**® HPV) is an automated qualitative *in vitro* test for the detection of human papillomavirus (HPV) DNA in patient specimens. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies HPV16 and HPV18 while concurrently detecting the other high risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) at clinically relevant infection levels. Specimens are limited to cervical cells collected in Roche Cell Collection

Medium (Roche Molecular Systems, Inc.), PreservCyt® Solution (Hologic Corp.) and SurePath™ Preservative Fluid (BD Diagnostics-TriPath).

Indications for use of **cobas®** HPV are:

A. **cobas®** HPV is indicated for use in screening patients with atypical squamous cells of undetermined significance (ASC-US) cervical cytology results to determine the need for referral to colposcopy.

B. **cobas®** HPV is indicated for use in screening patients with ASC-US cervical cytology results to assess the presence or absence of HR HPV genotypes 16 and 18.

C. **cobas®** HPV is indicated for use adjunctively with cervical cytology to assess the presence or absence of HR HPV types.

D. **cobas®** HPV is indicated for use adjunctively with cervical cytology to assess the presence or absence of HPV genotypes 16 and 18.

E. **cobas®** HPV is indicated for use as a first-line primary screening test to identify women at increased risk for the development of cervical cancer or presence of high-grade disease.

F. **cobas®** HPV is indicated for use as a first-line primary screening test to assess the presence or absence of HPV genotypes 16 and 18.

cobas® HPV can also be used with healthcare worker–instructed self-collected vaginal specimens collected in Roche Cell Collection Medium or PreservCyt® Solution.

The results from **cobas®** HPV, together with the physician's assessment of cytology history, other risk factors, and professional guidelines, may be used to guide patient management. The results of **cobas®** HPV are not intended to prevent women from proceeding to colposcopy.

Risk Class and Classification Rule:	Class C, as per EU Regulation 2017/746, Annex VIII, Rule 3 (a), (h)
Common Specifications:	No Common Specifications apply for the concerned device.
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 First Issued: 2021-04-29 Valid until: 2026-04-28

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: Rotkreuz, Switzerland

Date: 26 September 2022

DocuSigned by:
Nathalie Pankiw
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Nathalie Pankiw
Network Lead Molecular Lab
Pre-Market Quality

Place: Pleasanton, CA

Date: 20 September 2022

DocuSigned by:
Rita Hoady
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Rita Hoady
Network Lead Molecular Lab
Global Head of Regulatory Affairs