EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152 USA
Manufacturer SRN:	US-MF-000018910
Authorised Representative:	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland
Authorised Representative SRN:	IE-AR-000007610

Product:

Catalog Number	Product Trade Name
443982	BD Onclarity™ HPV Assay Reagent Pack
442840	BD Onclarity™ HPV Liquid Based Cytology Specimen (LBC) Diluent Tubes
441993	Control Set for the BD Onclarity™ HPV Assay
445026	Control Set for the BD Onclarity™ HPV Assay
443981	BD Onclarity™ HPV Extraction Reagent Trough for BD COR™
443983	BD Onclarity™ HPV Assay Diluent for BD COR™
444046	BD Onclarity™ HPV Liquid Based Cytology Specimen (LBC) Diluent Tubes
444869	BD Onclarity™ HPV Self Collection Diluent Tubes

Basic UDI-DI:

Catalog Number	Product Trade Name	Basic UDI-DI
443982	BD Onclarity™ HPV Assay Reagent Pack	038290BWOBDYNSBH
442840	BD Onclarity™ HPV Liquid Based Cytology Specimen (LBC) Diluent Tubes	038290DKZXVFSHK4
441993	Control Set for the BD Onclarity™ HPV Assay	038290JKQSRVNRK3
445026	Control Set for the BD Onclarity™ HPV Assay	038290DSSCXYXJHA
443981	BD Onclarity™ HPV Extraction Reagent Trough for BD COR™	038290HDXYQEYKGS

443983	BD Onclarity™ HPV Assay Diluent for BD COR™	038290YPWOTVFWXP
444046	BD Onclarity™ HPV Liquid Based Cytology Specimen (LBC) Diluent Tubes	038290ANJIWELF6J
444869	BD Onclarity™ HPV Self Collection Diluent Tubes	038290ILNNMLQLDB

Risk Class and Rule :

Catalog Number	Product Trade Name	Risk Class and Rule
443982	BD Onclarity™ HPV Assay Reagent Pack	Class C, Rule 3(a) & 3(h)
442840	BD Onclarity™ HPV Liquid Based Cytology Specimen (LBC) Diluent Tubes	Class C, Rule 3(a) & 3(h)
441993	Control Set for the BD Onclarity™ HPV Assay	Class C, Rule 3(a) & 3(h)
445026	Control Set for the BD Onclarity™ HPV Assay	Class A, Rule 5(c)
443981	BD Onclarity™ HPV Extraction Reagent Trough for BD COR™	Class A, Rule 5(c)
443983	BD Onclarity™ HPV Assay Diluent for BD COR™	Class A, Rule 5(c)
444046	BD Onclarity™ HPV Liquid Based Cytology Specimen (LBC) Diluent Tubes	Class A, Rule 5(a)
444869	BD Onclarity™ HPV Self Collection Diluent Tubes	Class A, Rule 5(c)

Intended Purpose:

Catalog Number	Product Trade Name	Intended Purpose
443982	BD Onclarity™ HPV Assay Reagent Pack	The BD Onclarity™ HPV Assay is an amplified DNA test for the qualitative detection of high-risk types of human papillomavirus (HPV). The assay detects all high-risk HPV types (16, 18, 31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68) and provides the capability for individually genotyping six high risk types (HPV 16,18, 31, 45, 51, and 52) and three genotype groups (33/58, 35/39/68, and 56/59/66). Cervical specimens that are tested with the BD Onclarity™ HPV Assay include the BD Onclarity™ HPV Cervical Brush Collection Kit, BD SurePath™ Preservative Fluid, and PreservCyt® Solution (using an aliquot that is removed prior to or after processing for either the BD SurePath™ or ThinPrep® Pap test). Self-collected vaginal specimens can also be tested with the BD Onclarity™ HPV Assay for cervical cancer screening. The BD Onclarity™ HPV Assay is indicated for use for routine cervical cancer screening as per professional medical guidelines, including triage of ASC-US cytology, co-testing (or adjunctive screen) with cytology, and HPV primary screening of women to assess the risk for cervical precancer and cancer. Patients should be followed-up in accordance with professional medical guidelines, results from prior screening, medical history, and other risk factors. The BD Onclarity™ HPV Assay is an automated assay performed with the BD COR™ System.
443981	BD Onclarity™ HPV Extraction Reagent Trough for BD COR™	
443983	BD Onclarity™ HPV Assay Diluent for BD COR™	
441993	Control Set for the BD Onclarity™ HPV Assay	The Control Set for the BD Onclarity™ HPV Assay contains Positive and Negative Controls that are intended for the qualitative Quality Control of the automated BD Onclarity™ HPV Assay on the BD Viper™ LT or BD COR™ Systems.
445026	Control Set for the BD Onclarity™ HPV Assay	

	444046	BD Onclarity™ HPV Liquid Based Cytology Specimen (LBC) Diluent Tubes	BD Onclarity™ Human Papillomavirus (HPV) Liquid-Based Cytology (LBC) Diluent Tubes are designed to allow for detection of Human Papillomavirus in gynecological specimens that are collected in BD SurePath™ Vial or PreservCyt® Solution and tested with the BD Onclarity™ HPV Assay on the BD Viper™ LT or BD COR™ Systems using an aliquot that is removed prior to or after processing for gynecological testing.
	442840	BD Onclarity™ HPV Liquid Based Cytology Specimen (LBC) Diluent Tubes	
	444869	BD Onclarity™ HPV Self Collection Diluent Tubes	BD Onclarity™ HPV Self Collection Diluent Tube is intended for the transfer and resuspension of self-collected vaginal specimens in the laboratory for testing with the BD Onclarity™ HPV Assay.
Notified Body:	BSI Group The Netherlands B.V. Say Building, John M. Keynesplein 9, 1066 EP Amsterdam, The Netherlands Notified Body Number: 2797		

We, as the manufacturer of the device(s) take sole responsibility for and hereby declare that the above-mentioned product(s) meet(s) the provisions of the following Directives/ Regulation(s):

- Regulation (EU) 2017/746 on *In vitro* Diagnostic Medical Devices.

Conformity Assessment Route:

☐ ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☒ ANNEX IX Full Quality System	EC CERTIFICATE No.: 750848 EC Certificate Expiration Date: 2027-05-22
☐ ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☐ ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
☒ ANNEX I & II+III	N/A

Common Specifications (CS):

Number:	Title:	Full or Partial Application:

Common Specifications have not been issued for these products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
443982	BD Onclarity™ HPV Assay Reagent Pack	Class C
442840	BD Onclarity™ HPV Liquid Based Cytology Specimen (LBC) Diluent Tubes	Class A*
441993	Control Set for the BD Onclarity™ HPV Assay	Class C
445026	Control Set for the BD Onclarity™ HPV Assay	Class C
443981	BD Onclarity™ HPV Extraction Reagent Trough for BD COR™	Class A*
443983	BD Onclarity™ HPV Assay Diluent for BD COR™	Class A*
444046	BD Onclarity™ HPV Liquid Based Cytology Specimen (LBC) Diluent Tubes	Class A*
444869	BD Onclarity™ HPV Self Collection Diluent Tubes	Class A*

*Class A non-sterile products are self-certified and therefore not reviewed by the Notified Body.

Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
On behalf of:	Becton, Dickinson and Company
Place of Issue:	Sparks, MD, USA
Date of Issue:	10-Nov-2022
Signature:	DocuSigned by: Anne Zavertnik Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 | 11:27:50 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial Release
02	Changed to New template CBI-058 FRM24-Revision 04. Added Intended Purpose for catalogs 441993, 445026, 443981, 444046, 442840, 443983 and 444869 as well. Risk rules has been deleted in Devices covered by this DoC. Updated “On behalf of” with Legal Manufacturer’s name. Formatting changes.