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 No.	Product Trade Name	Product Family
491248	BD SurePath PreCoat Slides	BD SurePath Liquid-based Pap Test Method
491453	BD Totalys MultiProcessor Consumables Kit	
491266	BD SurePath Manual Method Kit	
491332	BD Density Reagent	
491455	BD PrepMate Consumables Kit	
491454	BD PrepStain Consumables Kit	
491456	BD Totalys SlidePrep Consumables Kit	
491331	BD Syringing Pipettes	

Basic UDI-DI:

Catalog No.	Product Trade Name	Basic UDI-DI
491248	BD SurePath PreCoat Slides	038290MJZIOXBDJ7
491453	BD Totalys MultiProcessor Consumables Kit	038290FXHRELFOE9
491266	BD SurePath Manual Method Kit	
491332	BD Density Reagent	
491455	BD PrepMate Consumables Kit	

	491454	BD PrepStain Consumables Kit	
	491456	BD Totalys SlidePrep Consumables Kit	
	491331	BD Syringing Pipettes	038290YOWBADVMLL

Risk Class and Rule :

Catalog No.	Product Trade Name	Risk Class and Rule
491248	BD SurePath PreCoat Slides	Class A and Rule 5 (a)
491453	BD Totalys MultiProcessor Consumables Kit	
491266	BD SurePath Manual Method Kit	
491332	BD Density Reagent	
491455	BD PrepMate Consumables Kit	
491454	BD PrepStain Consumables Kit	
491456	BD Totalys SlidePrep Consumables Kit	
491331	BD Syringing Pipettes	

Intended Purpose:

Catalog No.	Product Name	Intended purpose
491266	**BD SurePath™ Manual Method Kit**	The BD SurePath™ Manual Method is a method for producing liquid-based cell preparations (LBPs). The BD SurePath Manual Method is intended as a replacement for the conventional Pap smear preparation method for use in cervical cancer screening. BD SurePath Preservative Fluid is an appropriate collection and transportation medium for gynecologic specimens tested with BD ProbeTec™ *Chlamydia trachomatis* (CT) Q^x and *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assay.

	491454 **491455** **491248** **491331** **491332**	**BD PrepStain™ Consumables Kit** **BD PrepMate™ Consumables Kit** **BD SurePath™ PreCoat Slides** **BD Syringing Pipettes** **BD Density Reagent**	The BD PrepStain™ System (formerly the AutoCyte® PREP System) is a liquid-based thin layer cell preparation process. The BD PrepStain System produces BD SurePath™ Liquid-based Pap Test slides that are intended as replacements for conventional gynecologic Pap smears. BD SurePath Liquid-based Pap Test slides (formerly AutoCyte PREP slides) are intended for use in the screening and detection of cervical cancer, pre-cancerous lesions, atypical cells and all other cytologic categories as defined by The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses. BD SurePath Preservative Fluid is an appropriate collection and transportation medium for gynecologic specimens tested with BD ProbeTec™ *Chlamydia trachomatis* (CT) Q^x and *Neisseria gonorrhoeae* (GC) Q^x Amplified DNA Assays. Refer to the assay package inserts for instructions on using BD SurePath Preservative Fluid to prepare specimens for use with these assays.
	491456	**BD Totalys™ SlidePrep Consumables Kit**	The BD Totalys™ SlidePrep is an automated liquid-based thin layer cell preparation system which produces BD SurePath™ Liquid-based Pap Test slides intended as replacements for conventional gynecologic Pap smears. BD SurePath™ Liquid-based Pap Test slides are intended for use in the screening and detection of cervical cancer, pre-cancerous lesions, atypical cells and all other cytologic categories as defined by The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses.

	491453	**BD Totalys™ MultiProcessor Consumables Kit**	The BD Totalys™ MultiProcessor is used in conjunction with the BD Totalys™ SlidePrep to prepare the BD SurePath™ Liquid-based Pap test, which is intended as a replacement for the conventional gynecologic Pap smear. The BD SurePath™ test is intended for use in the screening and detection of cervical cancer, pre-cancerous cervical lesions, atypical cells and all other cytologic categories as defined by The Bethesda System for Reporting Cervical/Vaginal Cytologic Diagnoses. The BD Totalys™ MultiProcessor automates the preparation of an enriched cell pellet from a cervical cytology specimen collected in a BD SurePath™ Collection Vial. The cell pellet produced by the BD Totalys™ MultiProcessor is transferred to the BD Totalys SlidePrep for further processing to prepare a BD SurePath™ slide. The BD Totalys MultiProcessor can be programmed to perform the optional withdrawal of a 0.5 mL aliquot from the BD SurePath Collection Vial, prior to the cell enrichment process, for ancillary testing indicated for use with the BD Totalys™ MultiProcessor. If a 0.5 mL aliquot is not withdrawn prior to cytology processing and slide preparation, the BD Totalys™ MultiProcessor can transfer a 0.25 to 1.5 mL aliquot of the residual material from the BD SurePath™ Collection Vial for ancillary testing indicated for use with the BD Totalys™ MultiProcessor. Additionally, the BD Totalys™ MultiProcessor may be used to re-process archived BD SurePath™ cytology specimens into cell pellets. The BD Totalys™ MultiProcessor can provide chain of custody information, linking the output cell pellets and molecular

			tubes to the originating BD SurePath™ Collection Vial.
Notified Body:	Not applicable, device(s) self-certified		
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.: N/A EC Certificate Expiration Date: N/A
☐ 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
491248	BD SurePath PreCoat Slides	Class A
491453	BD Totalys MultiProcessor Consumables Kit	Class A
491266	BD SurePath Manual Method Kit	Class A
491332	BD Density Reagent	Class A
491455	BD PrepMate Consumables Kit	Class A
491454	BD PrepStain Consumables Kit	Class A
491456	BD Totalys SlidePrep Consumables Kit	Class A
491331	BD Syringing Pipettes	Class A

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 | 11:30:43 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release.
02	Revision 04 Template Change, Product details updated in tabular format, Catalog No column included in Intended Purpose Section, 'Assigned BUDI' changed to 'Basic UDI-DI', Removed 'Not Available' in Common Specification table, Legal manufacturer name included in Authorised Signatory section, Class A mentioned for each catalog no. in Devices covered by this DoC table, and formatting changes.