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 name	Product Family
491335	BD CytoRich™ Blue Preservative	BD General Purpose Reagents
491336	BD CytoRich™ Red Preservative	
491337	BD SurePath™ Preservative Fluid	
491457	BD Alcohol Blend Rinse	
491458	BD Cytology Stain Kit	
491459	BD Non-GYN Stain Kit	

Basic UDI-DI:

Catalog No.	Product name	Basic UDI-DI
491335	BD CytoRich™ Blue Preservative	038290DGQNORZEAP
491336	BD CytoRich™ Red Preservative	038290DLFFGUMY4V
491337	BD SurePath™ Preservative Fluid	038290GDYWNUNZHN
491457	BD Alcohol Blend Rinse	038290EAHEHTYSYT
491458	BD Cytology Stain Kit	038290EEBLSFKQZP
491459	BD Non-GYN Stain Kit	038290EEWDJPBG5P

Risk Class and Rule :

	Catalog No.	**Product name**	**Risk Class and Rule**
	491335	BD CytoRich™ Blue Preservative	Class A and Rule 5 (a)
	491336	BD CytoRich™ Red Preservative	
	491337	BD SurePath™ Preservative Fluid	
	491457	BD Alcohol Blend Rinse	
	491458	BD Cytology Stain Kit	
	491459	BD Non-GYN Stain Kit	

Intended Purpose:	**Catalog No.**	**BD General Purpose Reagents**	**Intended purpose**
	491335	BD CytoRich™ Blue Preservative	BD CytoRich™ Blue Preservative is an alcohol-based preservative fluid intended for preservation of cytology cells in suspension and their subsequent preparation for cytological evaluation.
	491336	BD CytoRich™ Red Preservative	BD CytoRich™ Red Preservative is intended to preserve cells and small tissue fragments in suspension for cytological and histological examination. BD CytoRich Red™ Preservative lyses red blood cells and solubilizes proteins. The preserved samples are compatible with immuno-histochemical staining, and results are similar to those achieved with neutral buffered formalin.
	491337	BD SurePath™ Preservative Fluid	BD SurePath Preservative Fluid is intended for use in the collection and transportation of gynecologic specimens and for storage of residual cervical cytology specimens.

	491457	BD Alcohol Blend Rinse	BD Alcohol Blend Rinse is a general-purpose reagent which is a reagent grade alcohol solution that is intended to be used as a dehydrant and rinsing solution in the staining process of gynecologic and non-gynecologic cytology specimens.
	491458 491459	BD Cytology Stain Kit BD Non-GYN Stain Kit	The BD Cytology Stain and BD Non-GYN stain kits are reagents (multicolored stains) used for the purpose of staining (coloring) cells collected from the human body to be examined for diagnostic purposes.
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
491335	BD CytoRich™ Blue Preservative	Class A

491336	BD CytoRich™ Red Preservative	Class A
491337	BD SurePath™ Preservative Fluid	Class A
491457	BD Alcohol Blend Rinse	Class A
491458	BD Cytology Stain Kit	Class A
491459	BD Non-GYN Stain Kit	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 | 11:30:22 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release.
02	Revision 04 Template Change, Product family name included, 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 and formatting changes