EU DECLARATION OF CONFORMITY (DoC)

<table>
<tr><td>Manufacturer:</td><td>Becton, Dickinson and Company
7 Loveton Circle
Sparks, Maryland 21152
USA.</td></tr>
<tr><td>Manufacturer SRN:</td><td>US-MF-000018910</td></tr>
<tr><td>Authorised Representative:</td><td>Becton Dickinson Ireland Ltd.
Donore Road, Drogheda
Co. Louth, A92 YW26
Ireland</td></tr>
<tr><td>Authorised Representative SRN:</td><td>IE-AR-000007610</td></tr>
<tr><td>Product:</td><td>
<table>
<tr><th>Catalog Number</th><th>Product Trade Name</th><th>Product Family</th></tr>
<tr><td>491443</td><td>BD CytoRich™ Clear Collection Vial</td><td rowspan="2">BD Liquid Based Cytology Collection Vials</td></tr>
<tr><td>491452</td><td>BD SurePath™ Collection Vial Kit 500</td></tr>
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</td></tr>
<tr><td>Basic UDI-DI:</td><td>
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<tr><td>491443</td><td>BD CytoRich™ Clear Collection Vial</td><td>038290EMBDCDTHXN</td></tr>
<tr><td>491452</td><td>BD SurePath™ Collection Vial Kit 500</td><td>038290JMTAYLOWFJ</td></tr>
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<tr><td>Risk Class and Rule:</td><td>Class A and Rule 5 (c)</td></tr>
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Intended Purpose:	**Catalog Number**	**Product Trade Name**	**Intended Purpose**
	491443	BD CytoRich™ Clear Collection Vial	BD CytoRich™ Clear Collection Vial contains an alcohol-based preservative fluid intended for collection, preparation, and examination of cytology specimens from the human body for diagnostic purposes
	491452	BD SurePath™ Collection Vial Kit 500	The BD SurePath™ Collection Vial is designed for use with the BD PrepStain™ and BD Totalys™ Systems for the processing of BD SurePath™ Liquid-based Pap Tests. The BD SurePath Collection Vial contains an alcohol-based preservation solution that serves as a transport, preservative, and antibacterial medium for gynecologic specimens.
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
491443	BD CytoRich™ Clear Collection Vial	Class A
491452	BD SurePath™ Collection Vial Kit 500	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 | 11:30:37 PM GMT DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release.
02	Revision 04 Template change, Product Family name included, ‘Assigned BUDI’ changed to ‘Basic UDI-DI’, Removed ‘Not Available’ in Common Specification table, Legal manufacturer name updated in Authorised signatory section