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>491303</td><td>BD PrepStain™ Non-GYN Test Kit</td><td rowspan="2">BD CytoRich Non-GYN Test Method</td></tr>
<tr><td>491304</td><td>BD Totalys™ SlidePrep Non-GYN Test Kit</td></tr>
</table>
</td></tr>
<tr><td>Basic UDI-DI:</td><td>
<table>
<tr><th>Catalog Number</th><th>Product Trade Name</th><th>Basic UDI-DI</th></tr>
<tr><td>491303</td><td>BD PrepStain™ Non-GYN Test Kit</td><td>038290EOAUUUTCCJ</td></tr>
<tr><td>491304</td><td>BD Totalys™ SlidePrep Non-GYN Test Kit</td><td>038290LJNWQUIJJJ</td></tr>
</table>
</td></tr>
<tr><td>Risk Class and Rule:</td><td>Class A and Rule 5 (a)</td></tr>
<tr><td>Intended Purpose:</td><td>
<table>
<tr><th>Catalog Number</th><th>Product Trade Name</th><th>Intended Purpose</th></tr>
<tr><td>491303</td><td>BD PrepStain™ Non-GYN Test Kit</td><td rowspan="2">The BD PrepStain™ Non-GYN Test Kit and the BD Totalys™ SlidePrep Non-GYN Test Kit are consumables used in conjunction with the BD PrepStain™ and BD Totalys™ SlidePrep instruments to prepare BD CytoRich Non-GYN slides from non-gynecologic samples collected from the human body to be examined for diagnostic purposes.</td></tr>
<tr><td>491304</td><td>BD Totalys™ SlidePrep Non-GYN Test Kit</td></tr>
</table>
</td></tr>
<tr><td>Notified Body:</td><td>Not applicable, device(s) self-certified</td></tr>
</table>

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 this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
491303	BD PrepStain™ Non-GYN Test Kit	Class A
491304	BD Totalys™ SlidePrep Non-GYN Test 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 | 11:30:07 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', Intended Purpose updated in Table Format, Removed 'Not Available' in Common Specification table, Legal manufacturer name updated in Authorised signatory section