



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:	<table><tr><th>Catalog No.</th><th colspan="2">Product Trade Name</th></tr><tr><td>491346</td><td colspan="2">BD Totalys™ SlidePrep</td></tr></table>			Catalog No.	Product Trade Name		491346	BD Totalys™ SlidePrep	
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Risk Class and Rule:	Class A and Rule 5 (b)								
Intended Purpose:	<table><tr><th>Catalog No.</th><th>Product Trade Name</th><th>Intended Purpose</th></tr><tr><td>491346</td><td>BD Totalys™ SlidePrep</td><td>The BD Totalys™ SlidePrep (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 (formerly</td></tr></table>			Catalog No.	Product Trade Name	Intended Purpose	491346	BD Totalys™ SlidePrep	The BD Totalys™ SlidePrep (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 (formerly
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			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.
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): <ul style="list-style-type: none">• Regulation (EU) 2017/746 on <i>In vitro</i> Diagnostic Medical Devices.• Directive 2011/65/EU as amended (EU) 2015/863 on Restriction of the use of certain hazardous substances in electrical and electronic equipment as amended by Commission Delegated Directive 2015/863 (RoHS)			

Conformity Assessment Route:

<input type="checkbox"/> ANNEX IX Technical File Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input type="checkbox"/> ANNEX XI Production Quality System	EC CERTIFICATE No.: N/A EC Certificate Expiration Date: N/A
<input checked="" type="checkbox"/> 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
491346	BD Totalys™ SlidePrep	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:	<div>DocuSigned by: <i>Anne Zavertnik</i>  Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:30:30 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release.
02	Revision 04 Template change, '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