



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 Number	Product Name	
	212525	BD BBL™ Gram Crystal Violet	
	212526	BD BBL™ Gram Crystal Violet	
	212527	BD BBL™ Gram Decolorizer	
	212528	BD BBL™ Gram Decolorizer	
	212531	BD BBL™ Gram Safranin	
	212532	BD BBL™ Gram Safranin	
	212539	BD BBL™ Gram Stain Kit	
	212542	BD BBL™ Gram Iodine (Stabilized)	
	212543	BD BBL™ Gram Iodine (Stabilized)	
	212544	BD BBL™ Gram Basic Fuchsin	
	212545	BD BBL™ Gram Basic Fuchsin	
	212536	BD BBL™ Acridine Orange Stain	
	212537	BD BBL™ Acridine Orange Stain	
	231401	BD BBL™ Gram Slide	
Basic UDI-DI:			
	Catalog Number	Product Name	Basic UDI-DI
	212525	BD BBL™ Gram Crystal Violet	038290DJGZNWEXC5
	212526	BD BBL™ Gram Crystal Violet	
	212527	BD BBL™ Gram Decolorizer	



	212528	BD BBL™ Gram Decolorizer	
	212531	BD BBL™ Gram Safranin	
	212532	BD BBL™ Gram Safranin	
	212539	BD BBL™ Gram Stain Kit	
	212542	BD BBL™ Gram Iodine (Stabilized)	
	212543	BD BBL™ Gram Iodine (Stabilized)	
	212544	BD BBL™ Gram Basic Fuchsin	038290HVSHFJSEFW
	212545	BD BBL™ Gram Basic Fuchsin	038290DJGZNWEXC5
	212536	BD BBL™ Acridine Orange Stain	038290HTZXHANVNT
	212537	BD BBL™ Acridine Orange Stain	038290HUWBXHPBJ4
	231401	BD BBL™ Gram Slide	038290HZVTSFEJQL
Risk Class and Rule:	Class A, Rule 5 (a)		

Intended Purpose:	Product Family	Intended Purpose		
	BD BBL™ Gram Stain Kits and Reagents	Gram Stain Kits and Reagents are used to stain microorganisms from cultures or specimens by the differential Gram method.		
	BD BBL™ Acridine Orange Stain	BD BBL™ Acridine Orange Stain is recommended for use in the microscopic fluorescent detection of microorganisms in direct smears prepared from clinical and non-clinical materials. It is particularly useful in the rapid screening of normally sterile specimens, such as cerebrospinal fluid, where few organisms may be present and in the rapid examination of blood smears or smears containing proteinaceous material where differentiation of organisms from background material may be more difficult.		
	BD BBL™ Gram Slide	The BD BBL™ Gram Slide is used for evaluating and controlling the quality of Gram stain reagents and techniques.		
Notified Body:	Not applicable, devices 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. 				

Conformity Assessment Route:

<input type="checkbox"/> ANNEX IX Technical File Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input type="checkbox"/> ANNEX IX Full Quality System	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input type="checkbox"/> ANNEX X Type Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input type="checkbox"/> ANNEX XI Production Quality System	EC CERTIFICATE No.: EC Certificate Expiration Date:
<input checked="" type="checkbox"/> ANNEX I & II+III	N/A

Common Specifications (CS):

Number: <Version/Year>	Title:	Full or Partial Application: <Justification>
Not Available	Not Available	Not Available



Common Specifications have not been issued for this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
212525	BD BBL™ Gram Crystal Violet	Class A, Rule 5 (a)
212526	BD BBL™ Gram Crystal Violet	Class A, Rule 5 (a)
212527	BD BBL™ Gram Decolorizer	Class A, Rule 5 (a)
212528	BD BBL™ Gram Decolorizer	Class A, Rule 5 (a)
212531	BD BBL™ Gram Safranin	Class A, Rule 5 (a)
212532	BD BBL™ Gram Safranin	Class A, Rule 5 (a)
212539	BD BBL™ Gram Stain Kit	Class A, Rule 5 (a)
212542	BD BBL™ Gram Iodine (Stabilized)	Class A, Rule 5 (a)
212543	BD BBL™ Gram Iodine (Stabilized)	Class A, Rule 5 (a)
212544	BD BBL™ Gram Basic Fuchsin	Class A, Rule 5 (a)
212545	BD BBL™ Gram Basic Fuchsin	Class A, Rule 5 (a)
212536	BD BBL™ Acridine Orange Stain	Class A, Rule 5 (a)
212537	BD BBL™ Acridine Orange Stain	Class A, Rule 5 (a)
231401	BD BBL™ Gram Slide	Class A, Rule 5 (a)

Authorised Signatory:

Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
Place of Issue:	Sparks, MD, USA
Date of Issue:	29-Apr-2022
Signature:	<p>DocuSigned by:</p> <p><i>Anne Zavertnik</i></p> <p>Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 29-Apr-2022 5:07:17 PM BST DC6A638A32E64A8A91F9D8DE330F0415</p>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release