



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	
	231746	BD BBL™ DrySlide™ Oxidase	
	231748	BD BBL™ DrySlide™ Indole	
	231749	BD BBL™ DrySlide™ Nitrocefin	
	231747	BD BBL™ DrySlide™ PYR Kit	
Basic UDI-DI:	Catalog Number	Product Name	Basic UDI-DI
	231746	BD BBL™ DrySlide™ Oxidase	038290ATTYDTMFHK
	231748	BD BBL™ DrySlide™ Indole	038290OSFNPFNNGW
	231749	BD BBL™ DrySlide™ Nitrocefin	038290EWFBUOBKA6
	231747	BD BBL™ DrySlide™ PYR Kit	038290XBQCSHLMEM
Risk Class and Rule:	Class A, Rule 5 (a)		
Intended Purpose:	Product Family	Intended Purpose	
	BD BBL™ DrySlide™ Oxidase	BD BBL™ DrySlide™ Oxidase is used for determining the oxidase reaction of bacteria.	
	BD BBL™ DrySlide™ Indole	BD BBL™ DrySlide™ Indole is used for determining the indole reaction of bacteria.	



	BD BBL™ DrySlide™ Nitrocefin	BD BBL™ DrySlide™ Nitrocefin is used for detecting β-lactamase production by bacteria.
	BD BBL™ DrySlide™ PYR Kit	BD BBL™ DrySlide™ PYR Kit, containing BD BBL™ DrySlide™ PYR and BD BBL™ DrySlide™ PYR Color Developer, is used for the qualitative manual detection of hydrolysis of PYR in the rapid presumptive identification of group A streptococci and group D enterococci from pure culture. BD BBL™ DrySlide™ PYR, provided in an easy-to-handle slide format, and BD BBL™ DrySlide™ PYR Color Developer, provided in a reagent dispenser, accommodate up to four tests per slide/dispenser.
Notified Body:	Not applicable, devices self-certified	
<p>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):</p> <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
231746	BD BBL™ DrySlide™ Oxidase	Class A, Rule 5 (a)
231748	BD BBL™ DrySlide™ Indole	Class A, Rule 5 (a)
231749	BD BBL™ DrySlide™ Nitrocefin	Class A, Rule 5 (a)
231747	BD BBL™ DrySlide™ PYR Kit	Class A, Rule 5 (a)

Authorised Signatory:

Name & Title:	Anne Zavertrnik, Vice President, Regulatory Affairs
Place of Issue:	Sparks, MD, USA
Date of Issue:	29-Apr-2022
Signature:	<p>DocuSigned by: <i>Anne Zavertrnik</i></p> <p> Signer Name: Anne Zavertrnik Signing Reason: I approve this document Signing Time: 29-Apr-2022 5:10:51 PM BST DC6A638A32E64A8A91F9D8DE330F0415</p>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release