

**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 Number</th><th colspan="2">Product Name</th></tr><tr><td>231746</td><td colspan="2">BD BBL™ DrySlide™ Oxidase</td></tr><tr><td>231748</td><td colspan="2">BD BBL™ DrySlide™ Indole</td></tr><tr><td>231749</td><td colspan="2">BD BBL™ DrySlide™ Nitrocefin</td></tr><tr><td>231747</td><td colspan="2">BD BBL™ DrySlide™ PYR Kit</td></tr></table>			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	
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Risk Class and Rule:	Class A, Rule 5 (a)																	
Intended Purpose:	<table><tr><th>Product Family</th><th>Intended Purpose</th></tr><tr><td>BD BBL™ DrySlide™ Oxidase</td><td>BD BBL™ DrySlide™ Oxidase is used for determining the oxidase reaction of bacteria.</td></tr><tr><td>BD BBL™ DrySlide™ Indole</td><td>BD BBL™ DrySlide™ Indole is used for determining the indole reaction of bacteria.</td></tr></table>			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.									
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	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
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 <i>In vitro</i> Diagnostic Medical Devices.		

Conformity Assessment Route:

☐ ANNEX IX Technical File Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
☐ ANNEX IX Full Quality System	EC CERTIFICATE No.: EC Certificate Expiration Date:
☐ ANNEX X Type Examination	EC CERTIFICATE No.: EC Certificate Expiration Date:
☐ ANNEX XI Production Quality System	EC CERTIFICATE No.: EC Certificate Expiration Date:
☒ 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 Zavertnik, Vice President, Regulatory Affairs
Place of Issue:	Sparks, MD, USA
Date of Issue:	29-Apr-2022
Signature:	DocuSigned by:   Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 29-Apr-2022 5:10:51 PM BST DC6A638A32E64A8A91F9D8DE330F0415

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release