

**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 Trade 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 Trade 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>Catalog Number</th><th>Product Trade Name</th><th>Intended Purpose</th></tr><tr><td>231746</td><td>BD BBL™ DrySlide™ Oxidase</td><td>BD BBL™ DrySlide™ Oxidase is used for determining the oxidase reaction of bacteria.</td></tr><tr><td>231748</td><td>BD BBL™ DrySlide™ Indole</td><td>BD BBL™ DrySlide™ Indole is used for determining the indole reaction of bacteria.</td></tr></table>			Catalog Number	Product Trade Name	Intended Purpose	231746	BD BBL™ DrySlide™ Oxidase	BD BBL™ DrySlide™ Oxidase is used for determining the oxidase reaction of bacteria.	231748	BD BBL™ DrySlide™ Indole	BD BBL™ DrySlide™ Indole is used for determining the indole reaction of bacteria.						
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	231749	BD BBL™ DrySlide™ Nitrocefin	BD BBL™ DrySlide™ Nitrocefin is used for detecting β-lactamase production by bacteria.
	231747	BD BBL™ DrySlide™ PYR Kit	<p>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.</p> <p>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.</p>
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.: 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 these products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
231746	BD BBL™ DrySlide™ Oxidase	Class A
231748	BD BBL™ DrySlide™ Indole	Class A
231749	BD BBL™ DrySlide™ Nitrocefin	Class A
231747	BD BBL™ DrySlide™ PYR 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:	<div>DocuSigned by: <i>Anne Zavertnik</i>  Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:30:58 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial release
02	Revision 04 Template change, Catalog number and product trade name included in the Intended Purpose Section, removed rule from Devices covered by this DoC table, removed the word not available from common specifications table and formatting changes.