

**EU DECLARATION OF CONFORMITY (DoC)**

<b>Manufacturer:</b>	Becton, Dickinson and Company 7 Loveton Circle Sparks, Maryland 21152 USA																	
<b>Manufacturer SRN:</b>	US-MF-000018910																	
<b>Authorised Representative:</b>	Becton Dickinson Ireland Ltd. Donore Road, Drogheda Co. Louth, A92 YW26 Ireland																	
<b>Authorised Representative SRN:</b>	IE-AR-000007610																	
<b>Product:</b>	<table><tr><th>Catalog Number</th><th>Product Trade Name</th></tr><tr><td>240658</td><td>BD BBL™ Coagulase Plasma, Rabbit</td></tr><tr><td>240661</td><td>BD BBL™ Coagulase Plasma, Rabbit</td></tr><tr><td>240827</td><td>BD BBL™ Coagulase Plasma, Rabbit with EDTA</td></tr><tr><td>240826</td><td>BD BBL™ Coagulase Plasma, Rabbit with EDTA</td></tr></table>	Catalog Number	Product Trade Name	240658	BD BBL™ Coagulase Plasma, Rabbit	240661	BD BBL™ Coagulase Plasma, Rabbit	240827	BD BBL™ Coagulase Plasma, Rabbit with EDTA	240826	BD BBL™ Coagulase Plasma, Rabbit with EDTA							
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<b>Basic UDI-DI:</b>	<table><tr><th>Catalog Number</th><th>Product Trade Name</th><th>Basic UDI-DI</th></tr><tr><td>240658</td><td>BD BBL™ Coagulase Plasma, Rabbit</td><td>038290HLPGSWHS DR</td></tr><tr><td>240661</td><td>BD BBL™ Coagulase Plasma, Rabbit</td><td>038290HMHECOWF67</td></tr><tr><td>240827</td><td>BD BBL™ Coagulase Plasma, Rabbit with EDTA</td><td>038290HTGXGIXXH7</td></tr><tr><td>240826</td><td>BD BBL™ Coagulase Plasma, Rabbit with EDTA</td><td>038290HSEPDYIUDC</td></tr></table>	Catalog Number	Product Trade Name	Basic UDI-DI	240658	BD BBL™ Coagulase Plasma, Rabbit	038290HLPGSWHS DR	240661	BD BBL™ Coagulase Plasma, Rabbit	038290HMHECOWF67	240827	BD BBL™ Coagulase Plasma, Rabbit with EDTA	038290HTGXGIXXH7	240826	BD BBL™ Coagulase Plasma, Rabbit with EDTA	038290HSEPDYIUDC		
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<b>Risk Class and Rule :</b>	Class A, Rule 5(a)																	
<b>Intended Purpose:</b>	<table><tr><th>Catalog Number</th><th>Product Trade Name</th><th>Intended Purpose</th></tr><tr><td>240658</td><td>BD BBL™ Coagulase Plasma, Rabbit</td><td>BD BBL™ Coagulase Plasma, Rabbit and BD</td></tr></table>	Catalog Number	Product Trade Name	Intended Purpose	240658	BD BBL™ Coagulase Plasma, Rabbit	BD BBL™ Coagulase Plasma, Rabbit and BD											
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	240661	BD BBL™ Coagulase Plasma, Rabbit	BBL™ Coagulase Plasma, Rabbit with EDTA are used to qualitatively determine the pathogenicity of staphylococci using the direct tube method.
	240827	BD BBL™ Coagulase Plasma, Rabbit with EDTA	
	240826	BD BBL™ Coagulase Plasma, Rabbit with EDTA	
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"><li>Regulation (EU) 2017/746 on <i>In vitro</i> Diagnostic Medical Devices.</li></ul>			

### 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
240658	BD BBL™ Coagulase Plasma, Rabbit	Class A
240661	BD BBL™ Coagulase Plasma, Rabbit	Class A
240827	BD BBL™ Coagulase Plasma, Rabbit with EDTA	Class A
240826	BD BBL™ Coagulase Plasma, Rabbit with EDTA	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   11:27:27 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 in a table format, removed rule from Devices covered by this DoC table, removed the word not available from common specifications table and formatting changes.