

## EU DECLARATION OF CONFORMITY (DoC)

<b>Manufacturer:</b>	Becton Dickinson GmbH Tullastrasse 8 – 12 69126 Heidelberg, Germany		
<b>Manufacturer SRN:</b>	DE-MF-000018170		
<b>Authorised Representative:</b>	Not applicable		
<b>Authorised Representative SRN:</b>	Not applicable		
<b>Product:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	
	257303	BD Columbia CNA Agar with 5% Sheep Blood, Improved II	
	257306		
<b>Basic UDI-DI:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	<b>Basic UDI-DI</b>
	257303	BD Columbia CNA Agar with 5% Sheep Blood, Improved II	038290IUYVYBXQTC
	257306		
<b>Risk Class and Rule :</b>	Class A, Rule 5(a)		
<b>Intended Purpose:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	<b>Intended Purpose</b>
	257303	BD Columbia CNA Agar with 5% Sheep Blood, Improved II	BD Columbia CNA Agar with 5% Sheep Blood, Improved II is a selective medium used for the isolation of gram-positive microorganisms, especially staphylococci and streptococci, from clinical specimens
	257306		
<b>Notified Body:</b>	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"> <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 this product.

**Devices Covered by this DoC:**

SKU#	Device Name	Device Class
257303	BD Columbia CNA Agar with 5% Sheep Blood, Improved II	Class A
257306	BD Columbia CNA Agar with 5% Sheep Blood, Improved II	Class A

Authorised Signatory:	
<b>Name &amp; Title:</b>	Anne Zavertnik, Vice President, Regulatory Affairs
<b>On behalf of:</b>	Becton Dickinson GmbH
<b>Place of Issue:</b>	Sparks, MD, USA
<b>Date of Issue:</b>	10-Nov-2022
<b>Signature:</b>	<div>DocuSigned by: <i>Anne Zavertnik</i> Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022   11:27:35 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>



BD   Integrated Diagnostic Solutions	Document No. DS-ColCNA-5SB-ImpII-DOC
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**DECLARATION OF CONFORMITY Revision History:**

Version:	Detailed Change Description:
01	Initial Release
02	Revision 04 Template change, details in Intended Purpose updated to tabular format, removed not available from common specifications table and formatting changes