

## 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>	
	254042	BD Schaedler Agar with Vitamin K1 and 5% Sheep Blood	
	254084		
	255509	BD Brucella Blood Agar with Hemin and Vitamin K1	
	256506	BD CDC Anaerobe Agar with 5% Sheep Blood	
<b>Basic UDI-DI:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	<b>Basic UDI-DI</b>
	254042	BD Schaedler Agar with Vitamin K1 and 5% Sheep Blood	038290CKFLYWTC9C
	254084		038290CKFLYWTC9C
	255509	BD Brucella Blood Agar with Hemin and Vitamin K1	038290CRXATKFUDF
	256506	BD CDC Anaerobe Agar with 5% Sheep Blood	038290CUWUMRUFMJ
<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>
	254042	BD Schaedler Agar with Vitamin K1 and 5% Sheep Blood	BD Schaedler Agar with Vitamin K1 and 5% Sheep Blood is a highly nutritious, nonselective medium for the isolation and cultivation of fastidious strictly anaerobic bacteria from clinical specimens.
	254084		
	255509	BD Brucella Blood Agar with Hemin and Vitamin K1	BD Brucella Blood Agar with Hemin and Vitamin K1 is a highly nutritious medium for the isolation and cultivation of strict anaerobes from clinical specimens.
	256506	BD CDC Anaerobe Agar	BD CDC Anaerobe Agar with 5% Sheep Blood is a nonselective medium for the isolation and cultivation of fastidious,

	with 5% Sheep Blood	obligately anaerobic bacteria from clinical specimens.
<b>Notified Body:</b>	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
254042	BD Schaedler Agar with Vitamin K1 and 5% Sheep Blood	Class A
254084	BD Schaedler Agar with Vitamin K1 and 5% Sheep Blood	Class A
255509	BD Brucella Blood Agar with Hemin and Vitamin K1	Class A
256506	BD CDC Anaerobe Agar with 5% Sheep Blood	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   11:25:20 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div>

## DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial Release
02	Revision 04 Template change, removed not available from common specifications table and formatting changes