

## 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>	
	254546	BD Bifidobacterium Agar, Modified	
	254023	BD Schaedler Kanamycin-Vancomycin-Agar with 5% Sheep Blood	
	254077		
	254485	BD Schaedler CNA Agar with 5% Sheep Blood	
	254479	BD Wilkins Chalgren Agar with Amikacin with 7% Sheep Blood	
<b>Basic UDI-DI:</b>	<b>Catalog Number</b>	<b>Product Trade Name</b>	<b>Basic UDI-DI</b>
	254546	BD Bifidobacterium Agar, Modified	038290FTXYQFWLQ5
	254023	BD Schaedler Kanamycin-Vancomycin Agar with 5% Sheep Blood	038290EYQLIQSKY
	254077		
	254485	BD Schaedler CNA Agar with 5% Sheep Blood	038290FMBXBEDW6L
	254479	BD Wilkins-Chalgren Agar with Amikacin and 7% Sheep Blood	038290FDWOUMYTEF
<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>
	254546	BD Bifidobacterium Agar, Modified	BD Bifidobacterium Agar, Modified is a partially selective medium for the

			isolation of the <i>Bifidobacterium</i> flora in human stool specimens.
	254023	BD Schaedler Kanamycin-Vancomycin Agar with 5% Sheep Blood	BD Schaedler Kanamycin-Vancomycin Agar with 5% Sheep Blood is used in the selective isolation of <i>Bacteroides</i> , <i>Prevotella</i> and a variety of other gram-negative anaerobes from clinical specimens.
	254077		
	254485	BD Schaedler CNA Agar with 5% Sheep Blood	BD Schaedler CNA Agar with 5% Sheep Blood is a partially selective medium for the isolation of strictly anaerobic gram-positive cocci and other anaerobic gram-positive bacteria from clinical specimens.
	254479	BD Wilkins-Chalgren Agar with Amikacin and 7% Sheep Blood	BD Wilkins-Chalgren Agar with Amikacin and 7% Sheep Blood is a selective medium for the isolation of strictly anaerobic bacteria from clinical specimens. Due to the amikacin, most facultative organisms are inhibited.
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
254546	BD Bifidobacterium Agar, Modified	Class A
254023	BD Schaedler Kanamycin-Vancomycin Agar with 5% Sheep Blood	Class A
254077	BD Schaedler Kanamycin-Vancomycin Agar with 5% Sheep Blood	Class A
254485	BD Schaedler CNA Agar with 5% Sheep Blood	Class A
254479	BD Wilkins Chalgren Agar with Amikacin with 7% Sheep Blood	Class A

Authorised Signatory:	
Name & Title:	Anne Zavertnik, Vice President, Regulatory Affairs
On behalf of:	Becton Dickinson GmbH
Place of Issue:	Sparks, MD, USA
Date of Issue:	02-Oct-2023
Signature:	<div>DocuSigned by:   Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 02-Oct-2023   1:14:57 PM BST 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
03	Deletion of Cat. No. 254480, due to discontinuation, see CC-2023-326