

EU DECLARATION OF CONFORMITY (DoC)

Manufacturer:	Becton Dickinson GmbH Tullastrasse 8 – 12 69126 Heidelberg, Germany		
Manufacturer SRN:	DE-MF-000018170		
Authorised Representative:	Not applicable		
Authorised Representative SRN:	Not applicable		
Product:	Catalog Number	Product Trade Name	
	254447	BD MacConkey II Agar / Columbia CNA Agar with 5% Sheep Blood (Biplate)	
	254476	BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate)	
	257589		
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	254447	BD MacConkey II Agar / Columbia CNA Agar with 5% Sheep Blood (Biplate)	038290CAJRKZVC5B
	254476	BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate)	038290CDFBKOOVCB
	257589		
Risk Class and Rule :	Class A, Rule 5(a)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	254447	BD MacConkey II Agar / Columbia CNA Agar with 5% Sheep Blood (Biplate)	BD MacConkey II Agar / Columbia CNA Agar with 5% Sheep Blood (Biplate) is used for the selective isolation of gram-negative and gram-positive bacteria from clinical specimens.
	254476	BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate)	BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate) is used for the non-selective isolation of anaerobes and for the selective isolation of gram-negative anaerobic rods, especially
	257589		

			<i>Bacteroides</i> and <i>Prevotella</i> species and a variety of other gram-negative anaerobes from clinical specimens.
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:

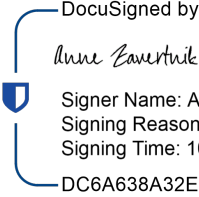
Common specifications have not been issued for these products.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
254447	BD MacConkey II Agar / Columbia CNA Agar with 5% Sheep Blood (Biplate)	Class A
254476	BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate)	Class A
257589	BD Schaedler Agar / Schaedler KV Agar with 5% Sheep Blood (Biplate)	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:	10-Nov-2022
Signature:	<div><div></div><div><div>DocuSigned by:</div><div>Anne Zavertnik</div><div> Signer Name: Anne Zavertnik Signing Reason: I approve this document Signing Time: 10-Nov-2022 11:37:06 PM GMT DC6A638A32E64A8A91F9D8DE330F0415</div></div></div>

DECLARATION OF CONFORMITY Revision History:

Version:	Detailed Change Description:
01	Initial Release
02	Revision 04 Template change, addition of catalog number to the tables, removed not applicable from common specifications table and formatting changes