

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	
	254010	BD Desoxycholate Agar	
	256500	BD Drigalski Lactose Agar	
	256525	BD Drigalski Lactose Agar with Ceftazidime	
	254014	BD EMB Agar, Modified	
	254016	BD Endo Agar	
	254074		
	254025	BD MacConkey II Agar	
	254078		
	254047	BD Salmonella Shigella Agar	
	254085		
	254055	BD XLD Agar	
	254090		
	Basic UDI-DI:	Catalog Number	Product Trade Name
254010		BD Desoxycholate Agar	038290CWSKEGWDE5
256500		BD Drigalski Lactose Agar	038290DPWWCLTKH9
256525		BD Drigalski Lactose Agar with Ceftazidime	038290DQCDSGOL5F
254014		BD EMB Agar, Modified	038290CXVTKOXRNH
254016		BD Endo Agar	038290CZDHUECIA8
254074			
254025		BD MacConkey II Agar	038290CZMJWGVXJ2
254078			
254047		BD Salmonella Shigella Agar	038290DAOCYIWQ46
254085			

	254055	BD XLD Agar	038290DCQMDAEU27
	254090		
Risk Class and Rule :	Class A, Rule 5(a)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	254010	BD Desoxycholate Agar	BD Desoxycholate Agar is a weakly selective differential medium for the isolation of Gram-negative enteric bacilli (mainly <i>Enterobacteriaceae</i>) from clinical specimens.
	256500	BD Drigalski Lactose Agar	BD Drigalski Lactose Agar is a selective and differential medium for the isolation of <i>Enterobacteriaceae</i> and certain nonfermenters from clinical specimens.
	256525	BD Drigalski Lactose Agar with Ceftazidime	BD Drigalski Lactose Agar with Ceftazidime is used for isolating and detecting <i>Enterobacteriaceae</i> resistant to broad spectrum cephalosporins
	254014	BD EMB Agar, Modified	BD EMB Agar, Modified (formula of Holt-Harris and Teague) is a slightly selective and differential medium for the isolation and differentiation of gram-negative enteric bacilli (<i>Enterobacteriaceae</i> and several other gram-negative rods) from clinical specimens.
	254016	BD Endo Agar	BD Endo Agar is a slightly selective and differential medium for the isolation and differentiation of <i>Enterobacteriaceae</i> and several other Gram-negative rods from clinical specimens.
	254074		
	254025	BD MacConkey II Agar	BD MacConkey II Agar is a selective and differential medium for the isolation and differentiation of <i>Enterobacteriaceae</i> and a variety of other Gram-negative rods from clinical specimens.
	254078		
	254047	BD Salmonella Shigella Agar	BD Salmonella Shigella Agar (SS Agar) is a selective and differential medium for the isolation of pathogenic enteric bacilli, especially those belonging to the genus <i>Salmonella</i> , from clinical specimens.
	254085		
	254055	BD XLD Agar	BD XLD Agar is a moderately selective and differential medium for the isolation and differentiation of gram-negative enteric pathogens (<i>Salmonella</i> and <i>Shigella</i>) from clinical specimens. It is especially suitable for the isolation of <i>Shigella</i> species.
	254090		



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
254010	BD Desoxycholate Agar	Class A
256500	BD Drigalski Lactose Agar	Class A
256525	BD Drigalski Lactose Agar with Ceftazidime	Class A
254014	BD EMB Agar, Modified	Class A
254016	BD Endo Agar	Class A
254074	BD Endo Agar	Class A
254025	BD MacConkey II Agar	Class A
254078	BD MacConkey II Agar	Class A
254047	BD Salmonella Shigella Agar	Class A
254085	BD Salmonella Shigella Agar	Class A
254055	BD XLD Agar	Class A
254090	BD XLD Agar	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 1:15:07 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. 212097, due to discontinuation, see CC-2023-326