

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	
	257574	BD MacConkey II Agar / Columbia CNA Agar	
	257584	Improved II with 5% Sheep Blood (Biplate)	
Basic UDI-DI:	Catalog Number	Product Trade Name	Basic UDI-DI
	257574	BD MacConkey II Agar / Columbia CNA Agar Improved	038290ENFUWDCCA8
	257584	II with 5% Sheep Blood (Biplate)	
Risk Class and Rule :	Class A, Rule 5(a)		
Intended Purpose:	Catalog Number	Product Trade Name	Intended Purpose
	257574	BD MacConkey II Agar / Columbia CNA Agar Improved II with 5% Sheep Blood (Biplate)	BD MacConkey II Agar / Columbia CNA Agar Improved II with 5% Sheep Blood (Biplate) is an improved medium used for the selective isolation of Gram-negative and Gram-positive bacteria from clinical specimens.
	257584		
Notified Body:	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"> 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 this product.

Devices Covered by this DoC:

SKU#	Device Name	Device Class
257574	BD MacConkey II Agar / Columbia CNA Agar Improved II with 5% Sheep Blood (Biplate)	Class A
257584	BD MacConkey II Agar / Columbia CNA Agar Improved II 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:**

DocuSigned by:

Anne Zavertnik

Signer Name: Anne Zavertnik

Signing Reason: I approve this document

Signing Time: 10-Nov-2022 | 11:32:18 PM GMT

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DECLARATION OF CONFORMITY Revision History:

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